Understanding DSCSA and How it Impacts You

There is no time to waste in getting prepared for the March 2016 enforcement of DSCSA

A Collaboration to Enrich the Future Leader of Maryland Pharmacy

Continuing Ed

Management of Type 2 Diabetes: Review of Drug Therapy and the Role of the Pharmacist

MPhA Annual Awards

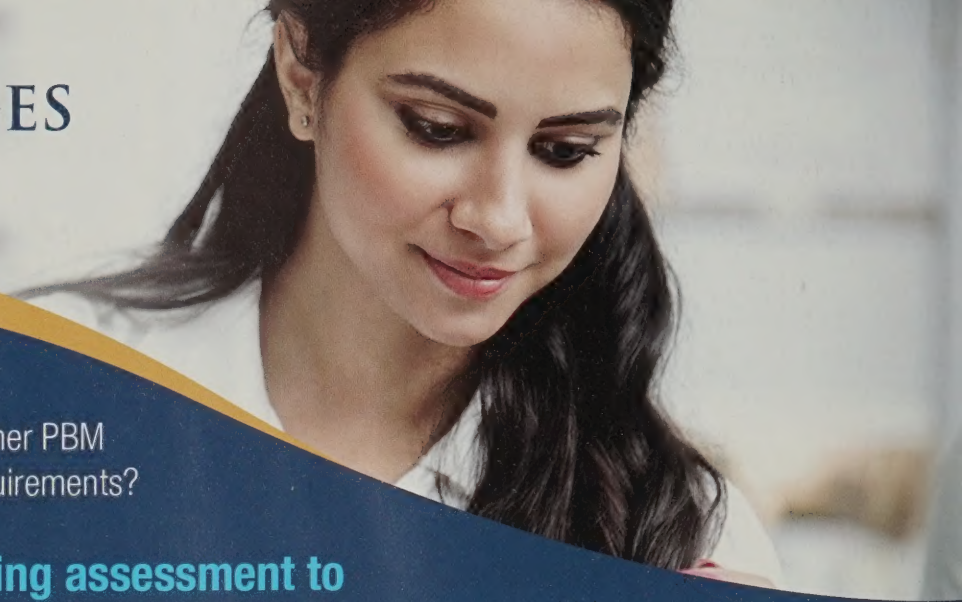
Individual professional excellence recognized during the MPhA Annual Convention

Maryland Pharmacist

FUTURE LEADERS OF PHARMACY

Diabetes Drug Therapy Management

R.J. HEDGES & ASSOCIATES



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PHARMACY CREDENTIALING ASSESSMENT

FWA

YES NO

- ☐ ☐ Are you conducting FWA Prevention training annually?
- ☐ ☐ Do you have an "Anti-Kickback" Policy & Procedure (P&P)?
- ☐ ☐ Do you have your entire staff completing Conflict of Interest forms annually?

Are you running OIG-GSA-SAM Exclusion Verifications each month on:

- ☐ ☐ Employees, Owners and Contractors
- ☐ ☐ Business Associates
- ☐ ☐ All vendors whose products are billed through Medicare

HIPAA

YES NO

- ☐ ☐ Do you have a HIPAA P&P manual/program in place?
- ☐ ☐ Has your Notice of Privacy Practice been updated since July 1, 2013?
- ☐ ☐ Do you maintain a breach assessment when the patient receives another patient's medication?

PATIENT SAFETY

YES NO

- ☐ ☐ Do you have a Quality Assurance Program?
- ☐ ☐ Are you enrolled in a Patient Safety Organization?

PHARMACY OPERATIONS

YES NO

- ☐ ☐ Are staff members trained on CMS 10147 Adherence if a "569 error" occurs?
- ☐ ☐ Do you have Policies and Procedures (P&P) to meet Pharmacy Medicare Part D credentialing requirements?
- ☐ ☐ Are you keeping annual records of all trainings (HIPAA & FWA with 10 years of retention)?
- ☐ ☐ Do you review your EQuiPP scores monthly?
- ☐ ☐ Do you have a Medication Adherence Program?

Do you have P&P's for:

- ☐ ☐ Usual and Customary
- ☐ ☐ Patient Counseling Practices
- ☐ ☐ Mis-fill Procedures
- ☐ ☐ Medication Recall Procedures
- ☐ ☐ Medication Expiration Procedures
- ☐ ☐ Generic/Brand Price Disclosures
- ☐ ☐ Demographics and Allergy Capture
- ☐ ☐ Partial Refills
- ☐ ☐ Return to Stock

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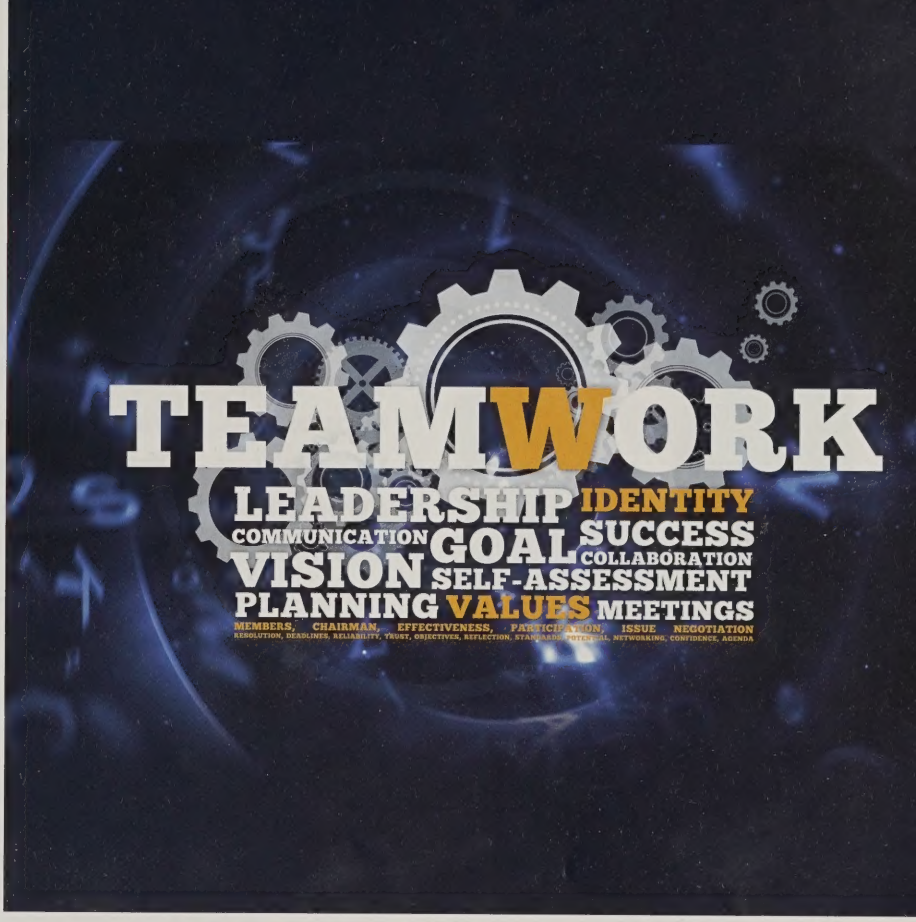

ADVERTISERS INDEX

President's Pad

"I believe that the state of MPhA is strong and growing thanks to your ongoing engagement and support. As a team, let's continue to carry out MPhA's mission: Strengthen the profession of pharmacy, advocate for all Maryland pharmacists, and promote excellence in pharmacy practice."

Dear Fellow MPhA Members,

Happy New Year. May 2016 bring you many blessings, especially health and happiness. Also, happy belated National Pharmacist Day which was on January 12. Did you know that was a day? I have been a pharmacist for over ten years and I did not know. My wife, Tanya, pointed that out to me. I always like to find reasons to celebrate our profession, so mark it on your calendar for next year!

I hope that you were able to attend MPhA's Open House in February to celebrate MPhA's new headquarters in Columbia. If not, please invite your pharmacy friends and colleagues to visit, especially if they are coming from across the country to attend the APhA Annual Meeting in Baltimore on March 4–7. There is plenty of history in the new space for everyone to appreciate.

Also, big congratulations to Executive Director Aliyah Horton, CAE. This is her one year anniversary since joining in January 2015. Aliyah has facilitated MPhA's move to the new headquarters and worked with members and staff to create a welcoming space. She has worked to provide more opportunities for member engagement and has transformed our new home into a venue that enhances the collaboration and professional development of the Maryland pharmacy community.

In addition, she has actively worked on behalf of MPhA to maintain long-term partnerships and build new networks of support in Annapolis as well as with the Department of Health and Mental Hygiene, the Board of Pharmacy, the Maryland Pharmacy Coalition and other affiliated communities. These relationships helped MPhA to have a more powerful voice in addressing challenges faced by different practice settings over the course of 2015 and will create new opportunities for 2016. Finally, she has worked with the MPhA leaders to create a strategic plan to guide our work over the next few years with a focus on governance, membership value, recruitment and retention.

In regards to MPhA's Strategic Plan, one of the three goals is to align MPhA governance to facilitate organizational growth and pharmacy community engagement. Thank you to all the members of the Board Compositions Task Force, led by Past MPhA Honorary President Dr. Lynette Bradley-Baker, for multiple meetings and great efforts to research board compositions of professional organizations and provide recommendations on changes to MPhA's Board of Trustees that will advance MPhA's long-term strategic objectives. One deliverable

Continued on next page

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MARYLAND PHARMACISTS ASSOCIATION

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Kelly Fisher

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We welcome your feedback and ideas for future articles for Maryland Pharmacist. Send your suggestions to Kelly Fisher: Maryland Pharmacists Association, 9115 Guilford Road, Suite 200, Columbia, MD 21046, call 443.583.8000, or email kelly.fisher@mdpha.com.

Special thanks to Graphtech, Advertising Sales and Design

already utilized was for the 2016 election. A guidance document was provided to the MPhA staff and Nominations Committee to assist in ensuring a formal process for MPhA elections and addressing diversity in election candidates. Stay tuned for specific recommendations, discussions, and vote on the Board compositions at the Annual Convention.

Membership engagement and regional outreach have continued to be a focus of my, or better yet, our presidency. Special thanks to several MPhA members and partners throughout the State for planning and/or hosting MPhA focus groups on membership value: Matt Balish, Tom Sisca, Darci Eubank, Brian Hose, Rosemary Botchway, the Eastern Shore Pharmaceutical Society, and the Primary Care Coalition of Montgomery County. The results and feedback will help with membership programs and recruitment efforts. In addition, please continue to ask your pharmacist colleagues who are not MPhA members to *"Ask Me 2 about MPhA"* in an effort to recruit members. Together, we can advocate better and stronger for our beloved profession. As always, if you have ideas or suggestions for programs or events, please reach out to me directly at htruong@abcforyourhealth.org.

For the upcoming spring, I am excited to share the launch of the MPhA Federal Pharmacists Network. Thank you to the co-founders LCDR Mathilda Fienkeng, CAPT Mary Kremzner, and CAPT (retired) James Bresette for all their leadership. Stay tuned for more information. Also, thank you to the New Practitioner Network and co-chairs Lauren Lakdawala and Sam Houmes for assisting with the bi-monthly membership program on April 21. This program will target the needs of recent and upcoming graduates. Check our website for more information as the date draws closer.

I believe that the state of MPhA is strong and growing thanks to your ongoing engagement and support. As a team, let's continue to carry out MPhA's mission: *Strengthen the profession of pharmacy, advocate for all Maryland pharmacists, and promote excellence in pharmacy practice."*

Sincerely,

Hoai An Truong

Hoai-An Truong, PharmD, MPH
President

Cover Story

By: James L. Bresette, PharmD
Shannon Riggins, PharmD Candidate 2017, University of Maryland Eastern Shore School of Pharmacy

A Collaboration to Enrich the Future Leaders of Maryland Pharmacy

On November 7, 2015, twenty-five student pharmacists and eighteen new practitioners and experienced pharmacists from across the state attended a successful collaborative leadership workshop hosted by the Pharmacists Leadership and Education Institute (PLEI) and sponsored by the Maryland Pharmacists Association (MPhA) Foundation. PLEI Board Members Gary Keil, PhD and Michael Negrete, PharmD led the all-day workshop while MPhA members Monica Healy and Tim Rocafort provided facilitation assistance.

Due to the work of Dr. Jim Bresette, Phi Lambda Sigma (PLS) funded a grant to support student pharmacists from the PLS chapters in each of the Maryland schools of pharmacy to participate in this workshop. This was the first time that all Maryland PLS chapters collaborated together. "Consistent with PLS mission and goals, this initiative was perfectly aligned to actively grow and prepare the next generation of Maryland pharmacists for leadership positions in their future work places and within the Maryland Pharmacist Association," said proudly by Dr. Jim Bresette.

Ha Phan, a third-year student at the University of Maryland School of Pharmacy, appreciated these efforts, "I enjoyed being able to interact with my fellow colleagues from different pharmacy schools who are also leaders in their schools. It was nice to see the overlap in core values and listen to what other students are passionate about."

The goal of the PLEI workshop was to discuss what it takes to be an effective leader, illustrate how to identify peoples' strengths and align them with appropriate tasks, and examine how values can be used to allocate limited time and resources to maximize meaning and purpose. Participants were asked not only to look at their strengths, but also their weaknesses in order to assess what areas could be causing them to falter as leaders. After participating in several activities aimed at self-analysis, participants were asked to share their conclusions through "pair sharing" and discuss the variances and similarities that came up as a group.

New practitioners who participated in the PLEI workshop

"I remember a particular moment when the PLEI facilitator asked everyone to raise their hand if conflict resolution DID NOT bother them. After seeing an overwhelming number of leaders raise their hands, I was shocked because I had never thought the topic of leadership could be made into a constructively positive experience. It then gave me a goal to work towards as a leader so that I, too, could feel that way," said Geoffrey Saunders, a second-year student at the University of Maryland Eastern Shore School Of Pharmacy.

During lunch, PLS chapter leaders from each of the schools of pharmacy sat together to talk about their chapters' experiences and goals for the upcoming year and to collect input about how to deal with challenges they might face. "This was an amazing

opportunity to learn from our fellow PLS members that we would not ordinarily have the opportunity to work with," said Brittany La-Viola, a fourth-year student at the Notre Dame of Maryland School of Pharmacy.

In one of the final activities of the day, each participant came up with a few goals for themselves and were asked to form an "accountabilibuddy" partnership to help achieve these goals. Ryan Button of the University of Maryland School of Pharmacy expressed his viewpoint, "It's about building interpersonal skills and interprofessional relationships. I look at it as a chance to reach out to someone that understands the ebbs and flows, the stresses and satisfactions, which we all experience. It's saying, 'I'm taking accountability for you taking care of yourself so that we can accomplish something special together.' It's a unique way to establish trust with someone."

After a long day of reflection, sharing, and goal-setting, Rite Aid Corporation generously sponsored a networking dinner where new practitioners and student pharmacists continued to interact with one another and share their perspectives on what had transpired for them throughout the day. It was clear that all participants found this workshop to be a valuable experience in developing their leadership skills.

Student pharmacists who participated in the PLEI workshop

"The PLEI workshop is by far the most ambitious project that the MPhA Foundation has sponsored. The success of the workshop is vital to the future of the MPhA Foundation and its fundraising efforts as it illustrates what can be accomplished when resources are available to fund such endeavors. Financial support of the MPhA Foundation is necessary in order to continue its mission of supporting student pharmacists, recognizing practice innovation and in this instance, enhancing philanthropy that supports leadership," said MPhA Foundation President Paul Holly.

On behalf of the students from Beta Lambda, Delta Beta, and Delta Nu chapters of PLS in Maryland, we owe a collective thank you to PLS National, MPhA Foundation, MPhA, Rite Aid Corporation, and PLEI for the incredible and enriching experience that this workshop has given Maryland student pharmacists and new practitioners as we move forward through the profession as the future leaders of pharmacy. **To donate to the MPhA Foundation, please visit www.marylandpharmacist.org.**

Save the Dates

3/5 — *Maryland Pharmacy Night at APhA Annual Meeting & Exposition* **March 5**, Baltimore, MD

3/17 — *March Board of Trustees Meeting* **March 17**, MPhA HQ

4/27 — *Script Your Future* **April 27**, MPhA HQ

5/12 — *May Board of Trustees Meeting* **May 12**, MPhA HQ

6/10-12 — *134th Annual Convention* **June 10-12**, Ocean City, MD

Visit www.marylandpharmacist.org to register online or for more information.

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MEMBER MENTIONS

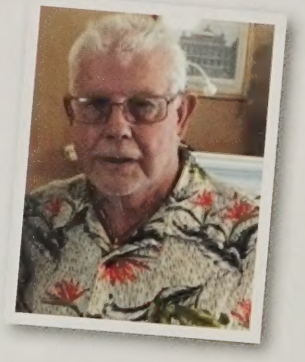
MPhA Past President **Dixie Leikach**, RPh, MBA has formed a non-profit organization, Pharmacy Ethics, Education and Resources (PEER), and is the President and CEO. The mission of PEER is to educate healthcare professionals on ethics to improve patient safety. The initial focus of PEER is to develop a series of continuing education programs focusing on the role of ethics in all areas of pharmacy and how ethics impacts patient safety. An ethics certificate program is also in development for those who would like to establish themselves as leaders in pharmacy ethics. If you are interested in more information about PEER, please visit www.PeerRx.org.

MPhA President **Hoai-An Truong**, PharmD, MPH has returned to the University of Maryland Eastern Shore School of Pharmacy and Health Professions as an Associate Professor in January 2016. Dr. Truong is a public health pharmacist, educator, and leader for over ten years. He has provided patient-centered care in an interprofessional collaborative model, part of the Primary Care Coalition of Montgomery County, focusing on medication therapy management to optimize medication use and improve healthcare access, quality, and outcomes for underserved populations. Hoai-An has served as coordinator and preceptor for pharmacy and physician assistant students on a health mission trip to Haiti. He has also mentored public health students on a needs assessment trip to Vietnam and recently became a co-founder of International Community Initiative.

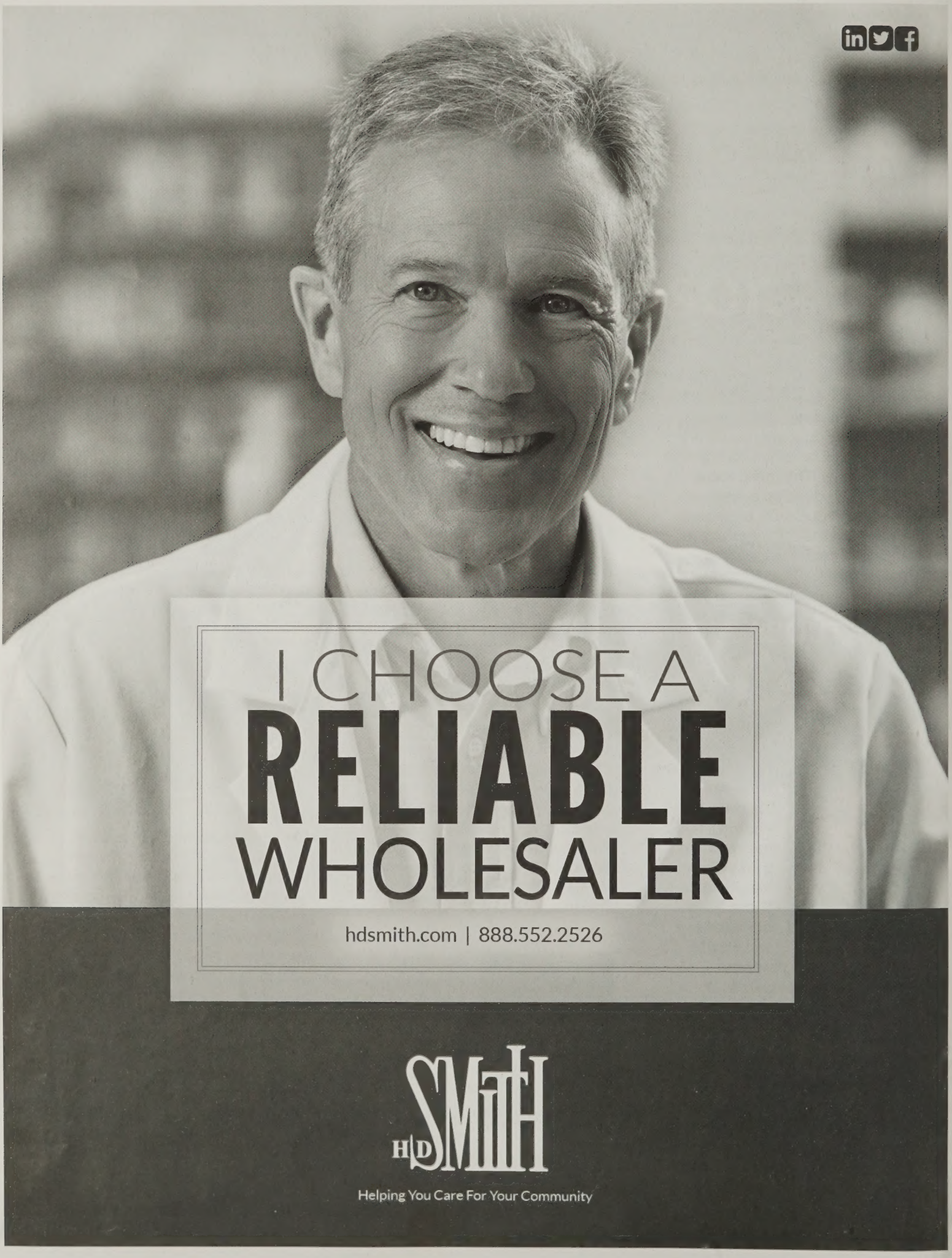
MPhA Trustee **Cherokee-Layson Wolf**, PharmD, BCACP, FAPhA has been recognized with the American Pharmacist Association-Academy of Student Pharmacists' (APhA-ASP) Outstanding Chapter Advisor Award. This award recognizes advisors of APhA-ASP chapters who have promoted with distinction the welfare of student pharmacists through various professional activities. Cherokee is an associate professor in the Department of Pharmacy Practice and Science and associate dean of student affairs at the University of Maryland School of Pharmacy.

Bethany DiPaula, PharmD, BCPP has been named a specialist member on the Board of Pharmacy Specialties' Council on Psychiatric Pharmacy. The psychiatric pharmacy specialist is often responsible for optimizing drug treatment and patient care by conducting such activities as monitoring patient response, patient assessment, recognizing drug-induced problems, and recommending appropriate treatment plans. Bethany is an associate professor in the Department of Pharmacy Practice and Science at the University of Maryland School of Pharmacy which is where she also received her Doctor of Pharmacy and completed her psychiatric pharmacy specialty residency.

In Memoriam



It is with great sadness we share that long-time member **Richard "Dick" Baylis**, PD, CGP, FASCP passed away on November 22, 2015. Dick was the MPhA President in 2003 and the 2005 recipient of the Seidman Distinguished Achievement Award. He graduated from Albany College of Pharmacy in New York and worked in community, hospital, and long-term care pharmacy. Dick was also very active in the Maryland Chapter of American Society of Consultant Pharmacist (MD-ASCP) and served as president. After he retired, he became the Executive Director of the Georgia-ASCP Chapter. MPhA and MD-ASCP held a Morning of Remembrance on December 12 at MPhA Headquarters.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Understanding DSCSA and How it Impacts **YOU**!

Drug Supply Chain Security Act (DSCSA) Readiness

While DSCSA went into effect over a year ago, its enforcement was delayed until March 1, 2016. MPhA knows that there is no time to waste in getting a solution in place. We have partnered with InfiniTrak, a track and trace software designed for independent pharmacists, to provide members with a deep discount on a timesaving solution to your DSCSA compliance needs. InfiniTrak helps you become compliant with the three key requirements of DSCSA and ensures that you remain compliant as the regulations continue to roll out. Here's what you need to know!

WHAT IS the Drug Supply Chain Security Act?

Created to ensure that our national drug supply is safe from counterfeit drugs, and that our pharmaceutical supply is safe and effective, DSCSA builds a nationwide electronic database that will track the ownership history of prescription drugs.

Verification

Do you have a business process in place to verify that your trading partners are properly licensed under federal or state law? Before you purchase a product from a wholesaler, you need to verify that the wholesaler is licensed to do business in your state. You also have to be sure your pharmacy is properly licensed - trading partners will be verifying you, as well.

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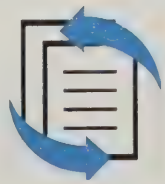
InfiniTrak includes a series of built-in work flows to help you analyze and investigate any possible tainted product.

Suspect Product Process

Do you have a process in place to handle any suspect or potentially counterfeit products? Do you have training available for your employees about how to be on the lookout for suspect products, how to investigate them, and how to quarantine them?

Transaction Data Management

Do you hold transaction data for 6 years and, if need be, have a system to retrieve the information for submission to federal or state authorities within 48 hours? If you are asked to research a product in response to the FDA regarding a potential suspect product, do you have a system to keep the information for an additional 6 years?



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2015 Recipients of the "Bowl of Hygeia" Award


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Alabama


Tom Van Hassel
Arizona


Nicki Hilliard
Arkansas


Robert Shmaeff
California


Sherman Gershman
Connecticut


Kevin Musto
Delaware


Fritz Hayes
Florida


Ron Stephens
Georgia


Kerri Okamura
Hawaii


Steven Bandy
Illinois


Jane Krause
Indiana


Richard Hartig
Iowa


Robert Nyquist
Kansas


Larry Stovall
Kentucky


Lloyd Duplantis
Louisiana


Kenneth McCall
Maine


Butch Henderson
Maryland


Paul Jeffrey
Massachusetts

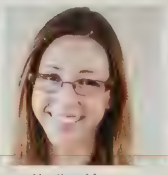

Derek Quinn
Michigan


Jenny Houglum
Minnesota


Robert Wilbanks
Mississippi


Richard Logan
Missouri


Gayle Hudgins
Montana


Heather Mooney
Nevada


Richard Crowe
New Hampshire


Edward McGinley
New Jersey


Amy Bachyrycz
New Mexico


Benjamin Gruda
New York


David Moody
North Carolina


Kevin Oberlander
North Dakota

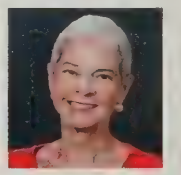

Danny Bentley
Ohio


Gordon Richards, Jr.
Oklahoma


Ann Zweber
Oregon


Thomas Mattei
Pennsylvania


Deborah Newell
Rhode Island


Sharm Steadman
South Carolina


Renee Sutton
South Dakota


Mac Wilhoit
Tennessee


Jim Cousineau
Texas

Marvin Orrock
Utah

John Beckner
Virginia

Gregory Hovander
Washington

Terri Smith Moore
Washington DC

David Flynn
West Virginia

Brian Jensen
Wisconsin

Randy Harrop
Wyoming

APhA FOUNDATION

NASPA

The Bowl of Hygeia award program was originally developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community. We offer our congratulations and thanks for their high example. The American Pharmacists Association Foundation, the National Alliance of State Pharmacy Associations and the state pharmacy associations have assumed responsibility for continuing this prestigious recognition program. All former recipients are encouraged to maintain their linkage to the Bowl of Hygeia by emailing current contact information to awards@naspa.us. The Bowl of Hygeia is on display in the APhA Awards Gallery located in Washington, DC.

2016 Maryland Pharmacists Association Awards

Recognizing Pharmacy Excellence

Each year, MPhA recognizes individual professional excellence during MPhA's Annual Convention. To nominate a deserving pharmacist for one of the awards described below, please visit us online to complete the nomination form at www.marylandpharmacist.org. You must include a brief statement and the nominee's current resume or curriculum vitae. Nominations are reviewed and selections are made by the Past Presidents Council. For consideration, nomination forms must be received by **Friday, March 25, 2016.**

Bowl of Hygeia Award

sponsored by the American Pharmacists Association Foundation and National Alliance of State Pharmacy Associations

Established in 1958, the Bowl of Hygeia Award recognizes pharmacists who possess outstanding records of civic leadership in their communities and encourages pharmacists to take active roles in their communities. In addition to service through their local, state, and national pharmacy associations, award recipients devote their time, talent, and resources to a wide variety of causes and community service. Any MPhA pharmacist member who has not already received the Bowl of Hygeia Award is eligible for nomination.

The Bowl of Hygeia is the most widely recognized international symbol for the pharmacy profession and is considered one of the profession's most prestigious awards. The Bowl of Hygeia has been associated with the pharmacy profession since 1796, when the symbol was used on a coin minted for the Parisian Society of Pharmacy. The bowl represents a medicinal potion and the snake represents healing.

Maryland Pharmacists Association Seidman Distinguished Achievement Award

Created by Henry Seidman, this award honors a Maryland pharmacist who has performed outstanding service over a number of years and whose service has resulted in a major impact on the pharmacy profession. Any MPhA pharmacist member who meets the criteria for this award is eligible for nomination.

Excellence in Innovation Award

sponsored by Upsher-Smith Laboratories, Inc.

Established in 1993, this award (formerly known as the Innovative Pharmacy Practice Award) aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing MPhA pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care is eligible for nomination.

Distinguished Young Pharmacist Award

sponsored by Pharmacists Mutual Companies

This award is presented each year to a pharmacist who has graduated within the past ten years and has made a significant contribution to the profession through service to a local, state, or national pharmacy organization. Any MPhA pharmacist member who has graduated from a school of pharmacy within the last ten years is eligible for nomination.

Maryland Pharmacists Association Mentor Award

This award recognizes individuals who encourage pharmacists, technicians, and/or student pharmacists in the pursuit of excellence in education, pharmacy practice, service, and/or advocacy. Any MPhA pharmacist member who meets the criteria for the award is eligible for nomination.

Cardinal Health Generation Rx Champions Award

sponsored by Cardinal Health Foundation

This award honors a pharmacist who has demonstrated outstanding commitment to raising awareness of the dangers of prescription drug abuse among the general public and the pharmacy community. Any MPhA pharmacist member who meets the criteria for the award is eligible for nomination.

Maryland Pharmacists Association Honorary President

An honorary position on the Board of Trustees is given to a person, not necessarily a pharmacist, who has worked for MPhA or Maryland Pharmacy over a long period of time. Any long standing contributor to the profession or the Association is eligible for nomination.

This year's Annual Convention will be on June 10-12 in Ocean City, MD at the Clarion Resort Fontainebleau Hotel. Online registration will open in the spring. Be sure to follow our Annual Convention hashtag, #MPhAAnnual, for news and updates!

Continuing Ed

Management of Type 2 Diabetes

Review of Drug Therapy and the Role of the Pharmacist

Zemen Habtemariam, PharmD Candidate 2016
Nina M. Bemben, PharmD, BCPS
Mary Lynn McPherson, PharmD, MA, BCPS, CDE
University of Maryland School of Pharmacy

In the United States, diabetes is a major chronic disease. An estimated 29 million Americans have diabetes and of these, nearly 28 million Americans have type 2 diabetes. Diabetes remains the seventh leading cause of death in this country, and people with diabetes are 1.7 times more likely to die from cardiovascular disease than people without diabetes.[1,2] Other potential complications of type 2 diabetes include cerebrovascular and peripheral vascular disease, retinopathy, nephropathy, and neuropathy.[3] In addition, hypoglycemic events associated with the disease account for approximately 282,000 emergency room visits every year.[1]

While the complications of diabetes certainly increase morbidity and decrease patient quality of life, diabetes also has an effect on patient mortality. Zhuo and colleagues conducted a study that helped measure the impact of diabetes on patient life expectancy.[4] They found among patients at age 40 years, those with diabetes lose an average 6.7 survival-adjusted life years compared to patients without diabetes.[4] Besides the direct effect on patient lives, diabetes also results in costs to the healthcare system and society at large. According to the Centers for Disease Control and Prevention (CDC), in 2012 direct medical costs attributable to diabetes were $176 billion and indirect costs, such as disability and reduced life expectancy, amounted to $69 billion.[1]

Diagnosis of Diabetes Mellitus

The American Diabetes Association (ADA) has developed four criteria for the diagnosis of diabetes mellitus and has established a diagnostic category referred to as prediabetes for patients at increased risk of developing diabetes.[5] Testing for asymptomatic people should be considered for children and adults who are overweight or obese and who have one or more risk factors for diabetes. Testing should begin at the age of 45 in all patients regardless of weight. When diagnosing diabetes, in the absence of a clear clinical diagnosis (e.g., hyperglycemic crisis), a second test is required to confirm diagnosis of diabetes mellitus. Criteria for diagnosing prediabetes and diabetes are as follows in the chart to the right.[5]

CRITERIA	PREDIABETES	DIABETES MELLITUS
Fasting plasma glucose (defined as no caloric intake for at least 8 hours)	100–125 mg/dl	≥ 126 mg/dl
2 hour post-prandial (following WHO guidelines for testing)	140-199 mg/dl	≥ 200 mg/dl
A1c	5.7-6.4%	≥ 6.5%
Random plasma glucose with classic symptoms of hyperglycemia		≥ 200 g/dl

Goals of Care

The ADA has made recommendations for glycemic control, as well as recommendations for blood pressure and cholesterol management. Glycemic targets are as follows, although targets may be customized for individual patients:[6]

- A1c < 7.0 %
- Preprandial capillary plasma glucose 80–130 mg/dl
- Peak postprandial (1–2 hours post beginning of meal) capillary plasma glucose < 180 mg/dl

As shown above, the ADA recommends achieving a glycosylated hemoglobin (HbA1c) of <7.0%.[3]

Blood glucose levels consistent with this therapeutic goal are <130 mg/dL for fasting glucose and <180 mg/dL for a two-hour post-prandial.[3] The ADA does recommend individualizing therapeutic goals depending on a patient's remaining life expectancy, duration of disease, presence of complications of diabetes, as well as other comorbidities.[3,6] For example, for a relatively young patient with newly diagnosed type 2 diabetes, no comorbidities or complications such as retinopathy or nephropathy, and a presumably long life-expectancy, more stringent control of blood glucose with a target HbA1c of 6.0-6.5% is appropriate.[3] Conversely, in an elderly patient with long-standing diabetes already suffering from complications such as retinopathy and multiple comorbidities, the benefits of stringent blood glucose control (decreased risk of microvascular complications) are not likely to outweigh the risks of hypoglycemia and adverse effects and a less stringent HbA1c goal of 7.5-8.0% may be reasonable.[3]

The ADA recommends people with diabetes and hypertension should be treated to a systolic blood pressure goal of <140 mmHg, although a goal of <130 mmHg may be more appropriate for selected patient populations.[7] Diastolic blood pressure should be <90 mmHg, or <80 mmHg for selected patients.[7] For people with diabetes under the age of 40 and no cardiovascular risk factors, no pharmacologic therapy is recommended to manage lipids. Patients over the age of 40 and those with cardiovascular risk factors should receive statin therapy (moderate or high intensity).[7]

Role of the Pharmacist

As medication experts, pharmacists are well trained to evaluate and improve drug regimens designed to maximize clinical, economic and humanistic outcomes from diabetes mellitus. As discussed later in this article, pharmacists may also provide patient education, both through patient counseling and Diabetes Self-Management Education (DSME) courses.

Learning Objectives

After completing this activity the participant will be able to:

1. Describe the prevalence of type 2 diabetes mellitus in the United States and list three potential complications of type 2 diabetes.
2. List at least five classes of drugs used to manage type 2 diabetes including efficacy, mechanism of action, and role in the management of type 2 diabetes mellitus.
3. Describe three strategies pharmacists may employ to assist in medication management for patients with type 2 diabetes mellitus.

Key Words

- diabetes
- diabetes self-management education
- type 2 diabetes
- antidiabetic agents

To provide the best care to our patients, pharmacists should be familiar with the appropriate treatment of diabetes and treatment plans consistent with evidence-based practice and patient-specific factors. In recent years, a dizzying number of medications have been introduced to the market for the management of diabetes; pharmacists are uniquely positioned to consider both patient and medication-related variables and make recommendations for optimal drug therapy that incorporate guidelines and evidence-based medicine. Tables 1 and 2 provide a description of commonly used glucose-lowering agents in the US.

Diabetes Drug Therapies

At the time of initial diagnosis of type 2 diabetes, most patients should be initiated on drug therapy with **metformin** (in addition to implementing lifestyle modification) due to its efficacy, safety, and accessibility.[8] Metformin typically does not cause hypoglycemia and has a neutral effect on weight. In addition, it may have cardiovascular benefits.[9] According to the ADA, metformin is the preferred first line agent for the management of type 2 diabetes unless patients have severe symptoms of hyperglycemia or severely elevated blood glucose levels (300-350 mg/dL or A1c >10%) at the time of initial diagnosis, in which case initial therapy should include insulin, with or without metformin.[8] If starting metformin therapy, the dose should be titrated up in order to achieve control of blood glucose levels; if a patient's blood glucose remains uncontrolled after three months, a second agent should be added to the drug therapy regimen.[8] Although the prescribing information states that metformin is contraindicated in men with a serum creatinine ≥1.5 mg/dL (≥1.4 mg/dL in women), current evidence supports using metformin in patients with some degree of renal impairment, however it should not be used in patients with an estimated creatinine clearance below 30 mL/min.[9]

While metformin is the appropriate initial therapy for most patients, the choice of subsequent agents is less clear and should be tailored to a specific patient. A sulfonylurea, thiazolidinedione (TZD), GLP-1 agonist, DPP-4 inhibitor, SGLT2 inhibitor, or basal insulin are all rational drug therapy options.[9] The choice of a particular agent should be individualized for each patient according to its adverse effect profile, cost, impact on patient weight, tolerable hypoglycemia risk, and patient preference.[3,9]

Sulfonylureas have long been used as add-on therapy in addition to metformin due to its efficacy in lowering HbA1c. However, unlike metformin, sulfonylureas are associated with weight gain and a risk of hypoglycemia.[3] In addition, sulfonylureas may have less efficacy as diabetes progresses, due to continued loss of pancreatic beta cell function.[3] Although similar to sulfonylureas, **meglitinides** may be preferred for patients with irregular meal patterns or those who experience post-prandial hypoglycemia with sulfonylurea therapy.[3] A potential disadvantage of meglitinides is increased frequency of dosing compared to sulfonylureas.[3]

Thiazolidinediones are another rational choice for a second agent in addition to metformin. Like metformin, it is not associated with a risk of hypoglycemia, and its therapeutic efficacy may be preserved longer than that of metformin and sulfonylureas.[3] However, these agents have been associated with rare, but serious adverse effects which may limit its utility in patients with comorbidities. Rosiglitazone may be associated with an increased risk of myocardial infarction and pioglitazone may be associated with an increased risk of bladder cancer.[3,9] Other adverse effects associated with the TZDs include weight gain and edema, which may precipitate heart failure exacerbations in those patients at risk.[3]

GLP-1 agonists are injectable agents, which act by stimulating insulin secretion, slowing gastric emptying, promoting satiety and reducing glucagon secretion.[3] Advantages of these agents include its potential to cause weight loss, efficacy in decreasing post-prandial glucose, and beneficial impact on some cardiovascular risk factors. Potential disadvantages include its non-oral route of administration, nausea and vomiting, and a possible risk of pancreatitis. In addition, medullary thyroid tumors have been observed in animal studies.[3,9]

Similar to GLP-1 agonists, **DPP-4** (dipeptidyl peptidase) **inhibitors** increase post-prandial incretin levels by preventing the degradation of GLP, although with a more modest HbA1c lowering effect.[3] Unlike the GLP-1 agonists, DPP-4 inhibitors have a neutral effect on weight.[3] It is generally well tolerated and does not increase the risk of hypoglycemia. However, it has been associated with angioedema and itching, and may also be associated with acute pancreatitis or increased hospitalizations due to heart failure.[9]

The **SGLT2** (sodium/glucose cotransporter 2) **inhibitors** are typically used in combination with metformin or DPP-4 inhibitors and have not yet been studied in combination with GLP-1 agonists.[5] Potential advantages of these agents include its association with decreases in weight and blood pressure and lack of hypoglycemia. However, SGLT2 inhibitors may cause polyuria leading to hypotension, increased LDL cholesterol, and infections of the genitourinary tract.[8]

Although not a first line choice, **alpha glucosidase inhibitors** may be used in combination with metformin. However, its place in therapy has traditionally been limited in the United States. The advantages of alpha glucosidase inhibitors include its efficacy

Pharmacists can provide patient education regarding diabetes management ... through provision of diabetes self-management education, or DSME, programs.

in controlling postprandial blood glucose levels, its lack of hypoglycemia risk, and a potential cardiovascular benefit.[9] However, the modest overall impact on HbA1c lowering, as well as poor patient tolerance due to adverse effects of flatulence and diarrhea, has limited its use.[9]

Due to the progressive nature of diabetes, most patients will eventually require insulin therapy to maintain blood glucose control.[3] Typically, insulin therapy is initiated with a basal insulin which may be the intermediate-acting neutral protamine Hagedorn or long-acting insulin glargine, insulin detemir, or insulin degludec.[8] If addition of basal insulin does not achieve adequate blood glucose control, particularly of post-prandial blood glucose levels, addition of a meal time or prandial insulin is often required.[3] Rapid-acting insulins such as lispro, aspart, or glulisine are frequently used, but short-acting human regular insulin may also be used.[8] Although highly effective across all stages of diabetes, initiation of insulin therapy is often resisted by patients and is associated with weight gain, hypoglycemia risk, and a need for patient education and training.[8]

Patient Education

As with any chronic disease, diabetes requires significant monitoring and patient education, which can be successfully provided by pharmacists. Due to the often complex medication regimen required to manage diabetes, provision of medication counseling by pharmacists is essential in order for patients to use their medications safely and effectively. In addition to medication therapy, lifestyle modifications are an essential component of diabetes management throughout the course of the disease. Patients should be educated to understand that although diabetes is a progressive disease, progression may be slowed through adherence to drug therapy and lifestyle modifications such as diet and exercise. Pharmacists are both willing and able to provide this patient education. For example, one study showed over 61.9 percent of pharmacists wanted to do more patient consultations and 58.5 percent of pharmacists stated they wanted to do more drug management activities.[10]

Pharmacists can provide patient education regarding diabetes management in a more formalized manner through provision of diabetes self-management education, or DSME, programs. These courses teach patients about diabetes management and what they should know to best look out for their own progress. DSME courses must be provided by a Certified Diabetes Educator; this credential can be obtained by pharmacists through completion of a certificate program.[11]

Conclusion

By maintaining a familiarity with therapeutic strategies for managing diabetes and evaluating the evidence supporting the use of an ever-increasing array of agents, pharmacists can help both patients and primary care providers effectively manage type 2 diabetes. Pharmacists also have an important role to play in helping patients manage this chronic disease, through patient counseling on effective medication use and lifestyle modifications. Pharmacists with specialized training in diabetes management may also provide DSME courses to give patients in-depth training on self-management of this chronic disease.

Sidebar Case

PM is a 56-year-old African American woman who presents to her primary care practitioner's office for her semi-annual routine visit. On questioning she states that she's been feeling "a triffle pooky" since her last visit. She says she has less energy than normal, and she has a pesky skin infection in the skin fold under her abdomen. She's been under a lot of stress because her sister was diagnosed with breast cancer and she's been helping take care of her.

The patient lives with her 58-year-old husband; she prepares their meals although she's been busy with her sister in the past four months or so that they have been eating a lot of frozen dinners. She acknowledges the frozen dinners have a lot of salt in them because she's often thirsty after dinner and during the night. She gets up once or twice every night to get a drink of water and to urinate. The patient tells you she has to be so careful about her diet. She really likes to eat a donut or bagel for breakfast, but two hours later she gets very shaky and her heart starts to pound. She has to eat another donut to make these symptoms dissipate.

PM tells you she isn't sleeping well because of the stress in her life and she needs to get up in the middle of the night one or more times.

Continues on next page

sidebar case

PMH:

- Dyslipidemia – 6 months (treated with dietary modification)
- Hypertension – 2 years
- Irritable bowel syndrome (diarrhea)
- GERD

Medications:

- Lisinopril 20 mg po qd
- Pepcid Complete – 1 tablet as needed
- Imodium as needed
- Lotrimin cream as needed

PE:

- Vital Signs: sitting BP 162/98 HR 84 BPM regular T: afebrile
- Ht: 5'2" wt: 280 lbs
- HEENT: Dry mucous membranes
- CV: S1, S2 no murmurs/rub appreciated
- Pulm: Clear to Auscultation
- Skin: Fungal skin infection 2 cm x 4 cm right abdomen

Laboratory data (two weeks ago)

- Random:
- Sodium 135 mEq/L; Potassium 4 mEq/L; Cloride 98 mEq/L; Bicarbonate 26 mEq/L; Blood urea nitrogen 18 mmol/L; Serum creatinine 1.1 mg/dL; Glucose 240 mg/dL
- Hemoglobin A1c = 9.5%
- LDL-C 137 mg/dl; HDL-C 32 mg/dL; TG 220 mg/dl; T cholesterol 227 mg/dl

Laboratory data (one week ago)

- Fasting: Glucose 186 mg/dl
- Hemoglobin A1c = 9.6%

You run the Pharmacotherapy Service in this primary care practice and the patient has been referred to you for management.

1. Can PM be diagnosed with diabetes?

a. Yes
b. No, she needs to take the 2 hour glucose tolerance test
c. No, she needs another fasting blood glucose drawn
d. No, she needs another A1c drawn

Yes, PM can be diagnosed with diabetes mellitus at this point. She presented with symptoms suggestive of hyperglycemia (feeling "a triffle pooky," less energy, persistent skin infections, increased thirst and urination including nocturia) and has a random plasma glucose over 200 mg/dl (240 mg/dl). Her A1c at the time of presentation also met the criteria for diabetes diagnosis (9.5%). A second A1c one week later was 9.6%, and a fasting plasma glucose of 186 mg/dl, which exceeds diagnostic criteria of a fasting plasma glucose of 126 mg/dl or higher.

2. What recommendations would you make for PM at this time?

a. Lifestyle modification (weight loss, exercise plan)
b. Metformin 500 mg po bid
c. Glyburide 10 mg po bid
d. A and B
e. A, B and C

According to the ADA guidelines, PM should begin lifestyle modifications immediately, along with metformin, therefore the answer is D. PM has no contraindications to metformin, and her serum creatinine is <1.4 mg/dl.

3. Which of the following values demonstrate PM has met her metabolic goals?

continued on page 20

Response	Fasting Plasma Glucose	Two hour post-prandial glucos	A1c	Blood pressure
a.	90 mg/dl	162 mg/dl	7.4%	138/84 mmHg
b.	135 mg/dl	210 mg/dl	8.2%	146/94 mmHg
c.	110 mg/dl	140 mg/dl	6.4%	130/92 mmHg
d.	60 mg/dl	120 mg/dl	5.8%	142/94 mmHg

The correct answer is C. The goal fasting plasma glucose is 80–130 mg/dl, 2 hour post-prandial glucose <180mg/dl, A1c <7% and BP <140/90 mmHg. Only answer C meets all these metabolic goals.

4. Despite the recommendation you made in question 2, PM has not achieved her blood glucose goal. Which of the following are possible options that may be added to her regimen?

a. Glipizide
b. Sitaliptin
c. Piogliazone
d. Exenatide
e. All of the above

The correct answer is E — all of the above. Per the ADA guidelines, any of these agents may be added to metformin (and of course continue lifestyle modifications). Some patients may even progress to triple therapy.

Table 1. Overview of Oral Antidiabetics[3,12]

Drug Class	Agent	Mechanism of Action	Dosing	Adverse Effects
Biguanides	Metformin (Glucophage®)	• Decreases hepatic glucose production and intestinal absorption (primary effect) • Increases insulin sensitivity to yield larger peripheral glucose uptake (secondary effect)	500mg PO twice daily, maximum 2550mg/day in 2-3 doses	Indigestion, flatulence, nausea, vomiting, diarrhea, asthenia, headache Vitamin B deficiency Lactic acidosis (rare)
Insulin (basal)	Insulin glargine (Lantus®)	• Regulates glucose metabolism via decreasing hepatic glucose production and stimulating glucose uptake by skeletal muscle	Total daily dose (initial) = 0.1 - 0.2 units/kg body weight. Titrated to glycemic goal.	Hypoglycemia, injection site reaction, rash, weight gain
	Insulin detemir (Levemir®)			
	Insulin degludec (Tresiba®)			
Sulfonylureas	Glipizide (Glucotrol®)	• Stimulates functional beta cells in pancreas	2.5-5mg PO once daily, Max=40mg/day in 1 to 2 divided doses	Heartburn, nausea, hypoglycemia, weight gain
	Glyburide (DiaBeta®)		1.25-5mg PO once daily, Max=20mg/day in 1 to 2 divided doses	Heartburn, nausea, hypoglycemia
Thiazolidinediones (TZDs)	Pioglitazone (Actos®)	• Decreases insulin resistance in liver and peripheral vasculature	15-30mg PO daily, Max=45mg/day	Edema, headache, weight gain, bone fracture, myalgia **Severe:** Heart failure, liver failure, Bladder cancer
	Rosiglitazone (Avandia®)		4mg PO daily, Max=8mg/day	

Continued on next page

Table 1. Overview of Oral Antidiabetics[3,12] *continued*

Drug Class	Agent	Mechanism of Action	Dosing	Adverse Effects
SGLT-2 Inhibitors	Canagliflozin (Invokana®)	• Blocks glucose reabsorption from proximal renal tubule, leading to increased glucose excretion	100mg PO daily, Max=300mg daily	Polyuria, vulvovaginal pruritis, genitourinary infections Volume depletion, hypotension, dizziness **Rare:** bone fracture, diabetic ketoacidosis, renal impairment (in patients w/o renal impairment)
	Empagliflozin (Jardiance®)		10mg PO daily (Initial); Max=25mg once daily	
DPP-4 Inhibitors	Sitagliptin (Januvia®)	• Blocks degradation of incretin hormones by DPP-4 (i.e., GLP)	100mg PO daily, Max=100mg daily	Hypoglycemia, headache, nasopharyngitis, angioedema/urticaria Acute pancreatitis
	Saxagliptin (Onglyza®)		5mg PO daily, Max=5mg daily	
GLP-1 Agonist	Exenatide (Byetta®)	• Acts as incretin mimetic; Stimulates glucose-dependent release of insulin and suppresses secretion of glucagon	5mcg SC twice daily	
	Liraglutide (Victoza®)		0.6mg SC once daily	Indigestion, decreased appetite, nausea, vomiting, diarrhea, headache Acute pancreatitis C-cell hyperplasia/medullary thyroid tumors in animals
Meglitinides	Repaglinide (Prandin®)	• Inhibits ATP-K+ channel on the membrane of the beta islet cell, which causes potassium efflux and calcium influx to induce insulin secretion	0.5mg PO two to four times daily before meals (Initial) 1-2mg PO two to four times daily before meals (Maintenance) Max=4mg/dose; 16mg/day	Hypoglycemia, weight gain, diarrhea, arthralgia, headache
	Nateglinide (Starlix®)		120mg PO three times daily at 30 minutes before meals	
Alpha-glucosidase inhibitors	Acarbose (Precose®)	• Lowers postprandial glucose by inhibition of pancreatic alpha-glucosidase hydrolase enzymes in the intestines	50-100mg PO three times daily; Max=100 mg TID (>60kg); Max=50 mg TID (< 60 kg)	Abdominal pain, flatulence, diarrhea
	Miglitol (Glyset®)		50-100mg PO three times daily; Max=100 mg three times daily	

Table 2. Classes of Oral Antidiabetics and Major Characteristics[8, 13]

Drug Class	Reduction in HbA1c	Hypoglycemic Risk	Weight Changes	Alpha-glucosidase	Costs
Metformin	1.0-1.5%	Low	Neutral	Gastrointestinal effects, lactic acidosis	Low
Sulfonylurea	1.0-1.5%	Moderate	+	Hypoglycemia	Low
Meglitinides	0.5-1.0%	Moderate	+	Gastrointestinal effects	Low
Thiazolidinedione	1.0-2.0%	Low	+	Edema, fractures, heart failure	Low
GLP-1 Agonist+	1.0-1.5%	Low	-	Gastrointestinal effects	High
DPP-4 Inhibitor	0.5-1.0%	Low	Neutral	Little to none	High
SGLT-2 Inhibitor	0.5-1.0%	Low	-	Genitourinary effects, dehydration	High
Alpha-glucosidase Inhibitors	0.5-1.0%	Low	Neutral	Gastrointestinal effects	Low
Insulin	≥ 1.5%	Highest	+	Hypoglycemia	Variable

HbA1c reduction is shown as an average percentage reduction. Weight gain is signified by a +, while weight loss is signified by a -. The cost column is designated by low (cost <$100) moderate (cost $100 to $199) and high (cost >$200) in regards to the wholesale acquisition cost for a 30-day supply.

MPhA News

WELCOME NEW MEMBERS

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This program is Knowledge Based — acquiring factual knowledge that is based on evidence as accepted in the literature by the health care professionals.

Directions for taking this issue's quiz:

This issue's quiz on **Management of Type 2 Diabetes: Review of Drug Therapy and the Role of the Pharmacist** can be found online at www.PharmCon.com.

(1) Click on "Obtain Your Statement of CE Credits for the first time.

(2) Scroll down to Homestudy/ OnDemand CE Credits and select the Quiz you want to take.

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(4) Click the Test link to take the quiz.

Note: If this is not the first time you are signing in, just scroll down to Homestudy/ OnDemand CE Credits and select the quiz you want to take.

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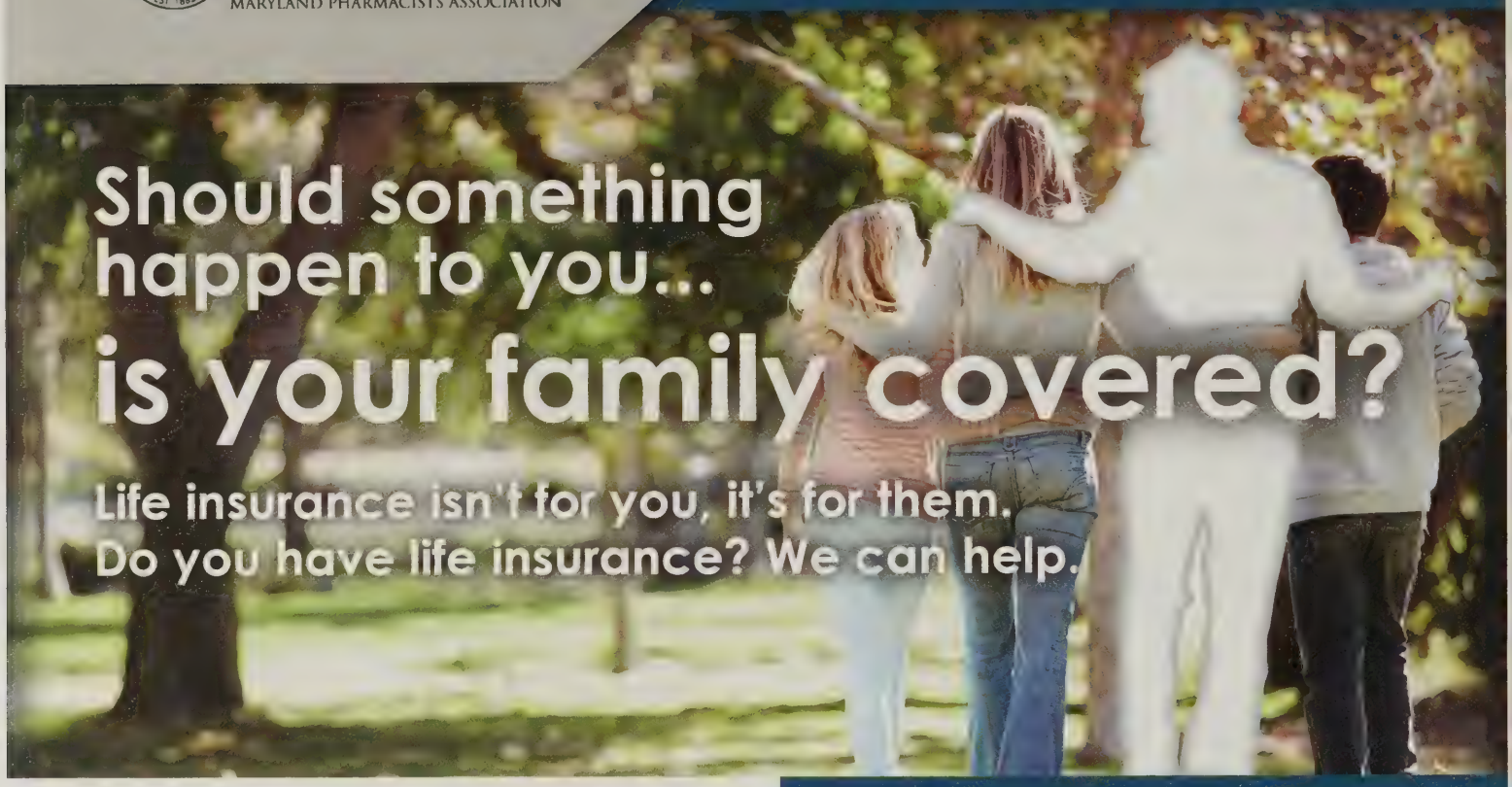

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Executive Director's Message

I AM GRATEFUL for the support from across the MPhA community including staff, elected leaders and trustees, Past Presidents, Deans, committee chairs, MPhA members, corporate sponsors, and partners who have shared their vision, the history and dreams for MPhA. Thank you for investing your time and expertise and allowing me to visit your practice settings and campuses.

Congratulations to the many members who were involved for nearly a decade in identifying the right location and design for MPhA's home in Columbia, Maryland. We continue to receive positive feedback from visitors on the facilities and location. If you haven't visited yet, the door is open!

"As I reflect on 2015, it is gratifying to be at the helm of an organization that is growing and changing to meet the needs of today's pharmacists, student pharmacists, residents and pharmacy technicians. Collectively, we have navigated through opportunities and challenges presented to our community in 2015."

VISION

In 2015 the Board of Trustees asserted its vision for MPhA *to be the voice representing all Maryland pharmacists as innovative and respected members of the healthcare team focused on the health and well-being of Maryland residents.* In order to achieve this vision, priority areas were identified in the areas of Governance, Membership Value, and Recruitment and Retention. Our mission is to strengthen the profession of pharmacy, advocate for all Maryland pharmacists and promote excellence in pharmacy practice.

A few highlights of how we are doing:

- **Aligning MPhA Governance to facilitate organizational growth and pharmacy community engagement**
  - In September 2015, the Board of Trustees approved MPhA's cultural core (our vision, mission and values).
  - In January 2016, the Board Composition Task Force presented recommendations to the Board of Trustees related to nomination and election policies and procedures as well as composition and representation on the Board of Trustees.
  - Operational structure and facilities in place that will continue to support and enhance the ability of MPhA to collaborate with strategic partners.
- **Enhancing Membership Value, proposition in the areas of advocacy, communication, continuing education, networking, and professional development/visibility.**
  - MPhA was fully engaged in the 2015 legislative session, actively participating in the passage of two Maryland Pharmacy Coalition bills that advanced and enhanced pharmacist scope of practice as well as emergency legislation designed to address pharmacy network restrictions.
  - MPhA has hired a lobbying firm to assist in building our recognition in Annapolis and forge relationships with elected leaders to advance MPhA legislative priorities
  - Communications, Professional Development and Membership Committees are working collaboratively to enhance MPhA's social media presence and to provide avenues for membership activity that address leadership, innovative practice, professional excellence and the collegiality of our organization.
  - Board meetings are now held bi-monthly with CE activities and membership events on the off months.
  - The *Monday Message* following the Board of Trustees Meetings includes meeting highlights and updates.
  - An online Membership Directory is now available on our website, which gives you the ability to connect with new and old colleagues, classmates and friends.
  - MPhA Meetings Committee launched a call for abstracts for the Annual Convention to ensure meeting content highlights diverse speakers and innovative content. Submit your topics and encourage others to as well. You can find the link in the *Monday Message* or on our website.
  - MPhA collaborated with the MPhA Foundation and various state agencies and national organizations to bring you Point-of-Care Training and leadership workshops as well as a newly implemented Health Information Exchange Task Force and collaborations on the Naloxone Standing Orders.
- **Increase Pharmacist Community Membership Recruitment and Retention**
  - Initiated the Pharmacists Month video contest and membership CE and recruitment drive.
  - Established new member benefits for financial education/webinars, loan consolidation, and Drug Security Supply Chain Act compliance.
  - MPhA leadership is conducting focus groups and outreach within different regions in the state and practice settings. Stay tuned for when we come to you!

There's much more to come. Cheers to an innovative and productive 2016!

Aliyah N. Horton, CAE
Executive Director

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MPhA News
An update on the 2016 Mid-Year Meeting, 16th Annual MPC Legislative Day, MPhA's Open [illegible] Annual [illegible]

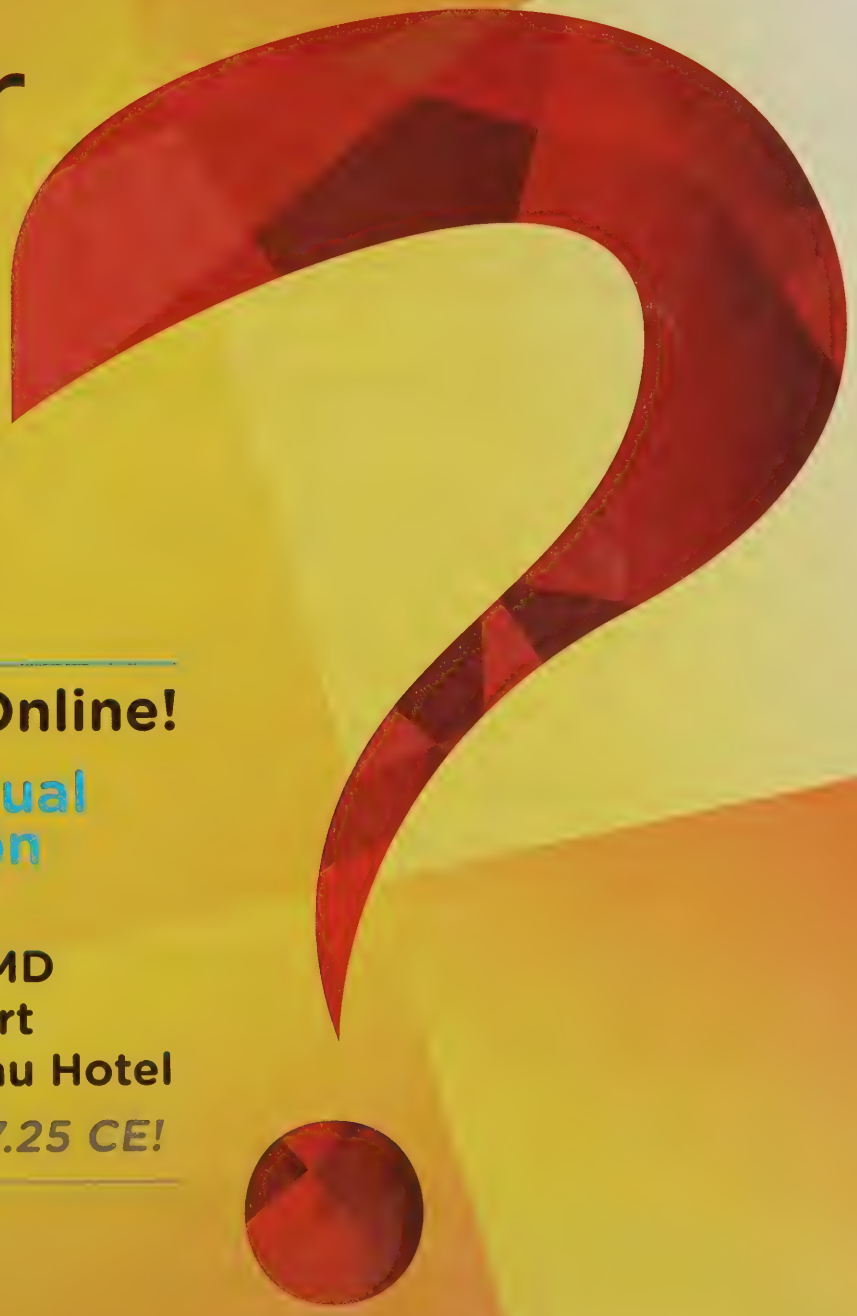
Provider Status
Why provider status is important, what it means and why we're working so hard to achieve it locally and nationwide

Continuing Education Article
A Review of Abuse-Deterrent Opiod Formulations and [illegible]

University of Maryland School of Pharmacy
Celebrating its 175th Anniversary

Maryland Pharmacist
SPRING 2016

Provider Status



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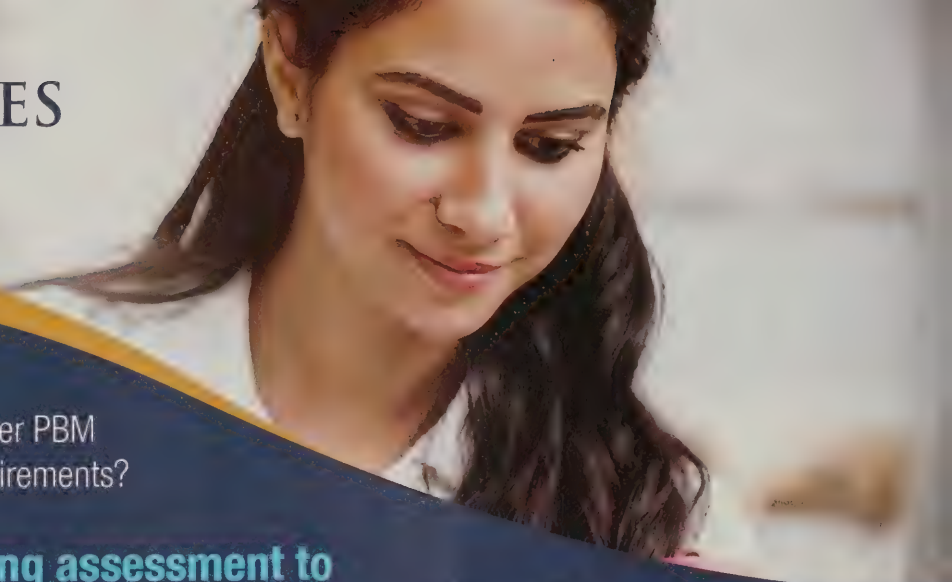

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PHARMACY CREDENTIALING ASSESSMENT

YES NO FWA

- ☐ Are you conducting FWA Prevention training annually?
- ☐ Do you have an "Anti-Kickback" Policy & Procedure (P&P)?
- ☐ Do you have your entire staff completing Conflict of Interest forms annually?

Are you running OIG-GSA-SAM Exclusion Verifications each month on:

- ☐ Employees, Owners and Contractors
- ☐ Business Associates
- ☐ All vendors whose products are billed through Medicare

YES NO HIPAA

- ☐ Do you have a HIPAA P&P manual/program in place?
- ☐ Has your Notice of Privacy Practice been updated since July 1, 2013?
- ☐ Do you maintain a breach assessment when the patient receives another patient's medication?

YES NO PATIENT SAFETY

- ☐ Do you have a Quality Assurance Program?
- ☐ Are you enrolled in a Patient Safety Organization?

YES NO PHARMACY OPERATIONS

- ☐ Are staff members trained on CMS 10147 Adherence if a "569 error" occurs?
- ☐ Do you have Policies and Procedures (P&P) to meet Pharmacy Medicare Part D credentialing requirements?
- ☐ Are you keeping annual records of all trainings (HIPAA & FWA with 10 years of retention)?
- ☐ Do you review your EQuiPP scores monthly?
- ☐ Do you have a Medication Adherence Program?

Do you have P&P's for:

- ☐ Usual and Customary
- ☐ Patient Counseling Practices
- ☐ Mis-fill Procedures
- ☐ Medication Recall Procedures
- ☐ Medication Expiration Procedures
- ☐ Generic/Brand Price Disclosures
- ☐ Demographics and Allergy Capture
- ☐ Partial Refills
- ☐ Return to Stock

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25 Corporate Sponsors

Winter 2016 Correction

The primary author was listed incorrectly on A Collaborat to *Enrich the Future Leaders of Maryland Pharmacy*. Shannon Riggins, PharmD Candidate 2017, University of Maryland Eastern Shore School of Pharmacy is the primary author. James I Bressette, PharmD is the secondary author

President's Pad

Dear Fellow MPhA Members,

Thank you for accepting my "ask" or invitation for you to be engaged with MPhA this past year. Thank you for embracing our theme of **"Ask Me 2 about MPhA"** and getting involved. And thank you for reminding our patients to "Ask your pharmacist about your medications."

It has been an amazing, enjoyable, and very fast-paced year. I believe we have achieved our goals and plans, which would not have happened without each of you. As I write my fourth president's message, it is appropriate to reflect upon our collective achievements in carrying out our mission and implementing the 2016 strategic plan, as well as upon ongoing efforts of the 20+ committees, taskforces, and networks from June 2015 to May 2016.

- Together we implemented the 2016 strategic plan with priorities in governance, membership retention and recruitment, and membership value proposition including advocacy, communications, continuing education, networking, and professional development/visibility
- Revised and recommended changes in by-laws as approved by the Board of Trustees in March 2016 and to be discussed/voted on at the House of Delegates at the convention
- Engaged members by changing the monthly Board of Trustees meetings to bi-monthly to facilitate bi-monthly membership programs:
  - o American Pharmacists Month Celebration with Medication Safety CE in October 2015
  - o Holiday Party in December 2015
  - o Advocacy Workshop in February 2016
  - o New Practitioners Workshop in April 2016
- Moved to the new Headquarters in Columbia, secured a tenant in the additional building suite, and hosted an Open House
- Had a successful Mid-Year Meeting in Columbia on January 31, 2016
- Enhanced the *Maryland Pharmacist* journal to all-color starting with the Winter 2016 issue
- Collaborated with the Maryland Pharmacy Coalition (MPC) to advocate for pharmacy-related bills during the 16th Annual MPC Legislative Day on February 18, 2016 and throughout the 2016 legislative session
- Organized three regional outreach CE programs and focus groups/surveys:
  - o Eastern Shore MD hosted by Eastern Shore Pharmaceutical Society on February 21, 2016
  - o Central MD hosted with Primary Care Coalition of Montgomery County on March 10, 2016
  - o Western MD hosted with Quad State Pharmacy Association on April 27, 2016
- Collaborated with the three schools of pharmacy to host a record breaking Maryland Pharmacy Night Reception during APhA's Annual Meeting in Baltimore, March 5, 2016. Over 400 guests attended and networked together
- Launched the Federal Pharmacy Network with a reception at the Food and Drug Administration on March 16, 2016
- Coordinated a Script Your Future Medication Adherence event on April 27, 2016
- Conducted two visits to the U.S. Capitol Hill on March 30, 2016 and April 29, 2016 to advocate and thank legislators for their support of pharmacists' provider status bills and efforts
- Collaborated with the MPhA Foundation to present student scholarships and awards for graduates at the three schools of pharmacy graduations
- Facilitated the Board's approval to be an affiliate organization with the Academy of Manage Care Pharmacists

With numerous initiatives and programs throughout the year, it would not be possible to recognize all individual volunteers on committees, taskforces, and networks in this message. It has also been so valuable to have partners such as the MPhA Foundation, three schools of pharmacy, and our corporate sponsors. We could not have done it without each of you. I thank you and look forward to celebrating with you during our Annual Convention in Ocean City.

I still need you. MPhA still needs you. Our pharmacy profession still needs you. Please continue to be engaged and invite fellow pharmacists, student pharmacists, and technicians to be involved. As I pass the torch to incoming MPhA President Kristen Fink, it continues to be an exciting time with great momentum for MPhA and pharmacy. I am confident you will support her as you have supported me. It has been and continues to be an exciting journey for us to serve together. I sincerely thank you for allowing me to serve as your 2015–16 President.

Sincerely,

Hoai An Truong

Hoai-An Truong, PharmD, MPH, FNAP
President

MPhA
MARYLAND PHARMACISTS ASSOCIATION

MANAGING EDITOR
Kelly Fisher

We welcome your feedback and ideas for future articles for Maryland Pharmacist. Send your suggestions to Aliyah Horton: Maryland Pharmacists Association, 9115 Guilford Road, Suite 200, Columbia, MD 21046, call 443.583.8000, or email aliyah.horton@mdpha.com

Special thanks to Graphtech, Advertising Sales and Design

What has MPhA been doing?
Member Mentions highlighted below!

16th Annual MPC Legislative Day

MPhA participated in the 16th Annual Maryland Pharmacy Coalition (MPC) Legislative Day on February 18, 2016. Legislative Day is the centerpiece of MPC's effort to send a unified pharmacy message to Maryland state legislators. This annual event is instrumental in advancing the pharmacy profession and facilitates pharmacists and student pharmacists in educating legislators on the importance of pharmacists and how we improve healthcare for our patients. Legislative Day consistently brings together over 300 participants who represent nearly all of the Maryland legislative districts and pharmacy practice settings.

The meeting kicked off with opening remarks by Senator John Astle (D-30). This year, MPC focused on issues relating to appropriate use of controlled substances by patients in Maryland, among many other pharmacy-related bills. MPC representatives from each organization developed consensus statements on pharmacy related bills that were introduced at that time. **For specific legislative updates, please see page 8.**

Student pharmacists with Carlo Sanchez, Member of Maryland House of Delegates, Prince George's County

Executive Director Aliyah Horton and President Hoai-An Truong with Pete Hammen, Chair of the House Health and Government Operations Committee

Thank you to all the student pharmacists for advocating for your profession and making sure your voices are heard!

Executive Director Aliyah Horton and President Hoai-An Truong with Mac Middelton, Chair of the Senate Finance Committee

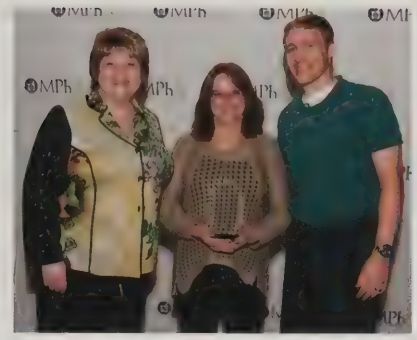
2016 Mid-Year Meeting

MPhA held its annual Mid-Year Meeting on January 31, 2016 at the DoubleTree Hilton in Columbia, Maryland. It was a full-day of live continuing education, networking, and professional recognition!

Continuing education sessions included hot topics such as:

- Medication safety **(See page 16 for a follow up on the Role of Ethics in Pharmacy)**
- Maryland's naloxone state-wide standing order information and implementation
- Pharmacy legislative and advocacy updates
- Clinical updates on biosimilars and medicinal cannabis

President Hoai-An Truong presented **Kim Morris** with MPhA's **2016 Pharmacy Technician of the Year Award** for her significant contributions to the expanding role of the pharmacy technician. Kim has been a pharmacy technician at Finksburg Pharmacy for over ten years. He also presented MPhA's **2015 Honorary President** award to **Thomas Menighan**, American Pharmacists Association Executive Vice President and Chief Executive Officer. Tom is a long-time MPhA member and resident of Maryland who has made a career of significantly contributing to the pharmacy profession. MPhA was pleased to work with him and APhA staff to support their Annual Meeting held in Baltimore.



Kim Morris accepting her award with MPhA members, Finksburg Pharmacist Manager Rai Cary and Owner Dixie Leikach

Thomas Menighan accepting his award with Executive Director Aliyah Horton and President Hoai-An Truong

MPhA's Open House

On February 20, 2016, MPhA welcomed members and partners at our official open house and ribbon cutting ceremony at our headquarters in Columbia, Maryland. President Hoai-An Truong presented **Murhl Flowers**, Relocation Committee Chair, and **Matt Shimoda**, Building Committee Chair, with a certificate of recognition for their outstanding generosity, dedication, and leadership to MPhA. Murhl and Matt were instrumental in getting MPhA a secure, centralized, and charming location that will support the needs of MPhA now and in the future. Thank you to everyone who came and celebrated our new home with us.

Ribbon cutting time! (left to right) Executive Director Aliyah Horton, Treasurer and Building Committee Chair Matt Shimoda, Relocation and History Committee Chair Murhl Flowers, MPhA Foundation President Paul Holly, and President Hoai-An Truong

Thank you to our Past Presidents! (back, left to right) Neil Leikach, Phil Cogan, Murhl Flowers, Paul Holly, Matt Shimoda, Howard Schiff, Current President Hoai-An Truong, Butch Henderson (sitting, left to right) Dixie Leikach. Christine Lee-Wilson. Jean Freels

APhA's Annual Meeting & Exposition

The American Pharmacists Association (APhA) held its Annual Meeting and Exposition on March 4-7, 2106 in Baltimore, Maryland. Several MPhA members were recognized with awards and appointments! It was great seeing MPhA members recognized on a national level for their pharmacy efforts and having a strong Maryland presence throughout the meeting!

(left to right) APhA CEO Thomas Menighan, Executive Director Aliyah Horton, Past President Cynthia Boyle, Congressman Elijah Cummings, President Hoai-An Truong, University of Maryland School of Pharmacy Dean Natalie Eddington, Past President Magaly Rodriguez de Bittner

Source: American Pharmacists Association

- ASP President **Elissa Lechtenstien** from the University of Maryland School of Pharmacy was elected APhA-ASP Member-at-Large. Elissa was also recognized as a recipient for the 2016 APhA Foundation's Mary Louise Andersen Scholarship.
- **Salematou Traore** from University of Maryland Eastern Shore School of Pharmacy was recognized as the recipient for the 2016 APhA Foundation's Mary Munson Runge Scholarship.
- **Carolyn Cooper** from the University of Maryland Eastern Shore School of Pharmacy was selected as a recipient of the Ron Williams Memorial Fund Scholarship.
- Past President **Butch Henderson** was recognized as the 2015 Bowl of Hyegia Award recipient.
- Trustee **Cherokee Layson-Wolf** was honored with the APhA-ASP Outstanding Advisor Award.
- **Joey Mattingly** was nominated as candidate for speaker-elect of APhA's House of Delegates.
- **Notre Dame of Maryland University School of Pharmacy** was recognized with the Outstanding IPSF Activity Award.
- **University of Maryland School of Pharmacy** APhA-ASP Chapter won second runner up of the Division A Chapter Achievement Award.

2016 Legislative Session Report

The 436th session of the Maryland General Assembly adjourned sine die at midnight on April 11, 2016 after 90 days of meetings to consider more than 2,800 bills and resolutions. By contrast, last year only roughly 2,200 bills were submitted making this a very busy year with committees meeting well into the evening and late night hours to review legislation.

Major Topics

Each year there are a few topics that dominate the debate in Annapolis. Below you will find more information on some of the major topics debated this session. These topics cover only a small fraction of the total legislation considered.

Justice Reinvestment Act

After debate over the entire legislative session, a bill was passed on the final day will change how criminal justice is administered in the state. The bill includes a provision that removes the mandatory minimums for providing bogus prescriptions but sets maximum sentences of 20 years for the first and second offenses, 25 years for the third and 40 years for the fourth.

Drunk and Drugged Driving

The most debated bill on this topic went by the name of "Noah's Law" in memory of Montgomery County Police Officer Noah Leotta who was killed by a drunk driver late last year. The legislation would require ignition interlock devices in the cars of all drunk driving offenders. Noah's Law passed on the final day of the legislative session after lengthy debate about the details of implementation of the bill.

Earned Sick Leave

For supervisors and business owners, earned sick leave has been introduced without successful passage for several years. This year, for the first time, it was passed in the House of Delegates. The Senate vote came down to the final hours of the legislative session with the bill ultimately not passing. The bill would require that all companies with more than 14 employees provide earned sick leave at a rate no less than one hour per every thirty hours worked.

Prescription Drug Monitoring Program

Legislation was passed that will create a prescription drug monitoring program to help curb the over-prescription of opiates and other narcotics. This is part of a number of bills aimed at reducing the illegal drug use epidemic in the state, a priority of the Hogan Administration. MPhA worked to remove pharmacist requirements for mandatory querying prior to dispensing. The bill does require pharmacists to be registered in the system. A more substantive review of the bill will be provided in future publications.

MPhA INTERIM ACTIVITIES

G.S. Proctor & Associates was committed to assuring MPhA's advocacy participation with our legislative priorities during the 2016 legislative session – Prescription Drug Monitoring Program legislation, specialty drugs legislation and other related bills. They are working to assure future successes by establishing relationships with key officials during the interim. G.S. Proctor committed meetings for MPhA's Executive Director to meet with Delegate Nic Kipke (specialty drugs bill sponsor), Senator Mac Middleton (PDMP bill sponsor), House Speaker Michael E. Busch, Senate President Mike Miller and Brian Frosh, Attorney General. These meetings will allow MPhA to provide information on issues and concerns and share legislative and regulatory priorities.

MPhA BILL UPDATE

The following chart includes bills reviewed by MPhA's Advocacy Committee and tracked by G.S. Proctor & Associates during the 2016 Legislative Session. If there were bills in the 2016 legislative session that you believe MPhA should have tracked or taken a position on, you are encouraged to join the Advocacy Committee and provide your insight and perspective. Just add the Advocacy Committee in your member profile. If you need assistance, please contact MPhA at 443-583-8000.

Status 2016 Regular Session

Title	Primary Sponsor	Status
HB0015 Harford County—Suspected Overdoses—Reporting Requirement Requiring specified individuals who treat or are in charge of a hospital that treats an individual in Harford County for a suspected overdose that was caused or shows evidence of having been caused by a Schedule I controlled dangerous substance to notify the county sheriff, county police, or the Department of State Police of the suspected overdose within 48 hours after the individual is treated; requiring that a report of a suspected overdose include specified information; and establishing a specified penalty.	Delegate Szeliga	Unfavorable
HB0024 Public Health—Overdose Response Program—Educational Training Program Requirement Requiring educational training for an Overdose Response Program overseen by the Department of Health and Mental Hygiene to include training in the requirement to immediately contact medical services after the administration of naloxone by a certificate holder instead of training in the importance of contacting emergency medical services.	Delegate Szeliga	Unfavorable
HB0104 Medical Cannabis—Written Certifications—Certifying Providers Authorizing specified dentists, podiatrists, nurse midwives, and nurse practitioners, in addition to physicians, to issue written certifications to qualifying patients by substituting the defined term "certifying provider" for "certifying physician" as it relates to laws governing medical cannabis; establishing that specified providers must be in good standing with the regulatory board regulating the licensing and certification of specified providers; providing for a delayed effective date; etc.	Delegate Morhaim	Returned Passed eliminate mid-wives—amendment was rejected
HB0006 Criminal Law–Improper Prescription of Controlled Dangerous Substance Resulting in Death Prohibiting an authorized provider from prescribing, administering, distributing, or dispensing a controlled dangerous substance to a person if such practice is not in conformity with specified provisions of law and the standards of the authorized provider's profession relating to controlled dangerous substances and the person's use or ingestion of the controlled dangerous substance is a contributing cause of the person's death; establishing penalties of up to 20 years in prison or a fine of up to $100,000 or both; etc.	Delegate Young, K.	Unfavorable
HB0117 (SB0469) **State Board of Pharmacy—Licensure Requirements for Pharmacists—Proof of Proficiency in English** Providing that, for applicants for a license to practice pharmacy, graduation from a recognized English-speaking professional school accredited by the Accreditation Council for Pharmacy Education is acceptable proof of proficiency in the oral communication of the English language.	Delegate Barron	Returned Passed
HB0437 (SB0537) **Department of Health and Mental Hygiene—Prescription Drug Monitoring Program—Modifications** Requiring that specified authorized providers and prescribers be registered with the Prescription Drug Monitoring Program before obtaining a new or renewed controlled dangerous substance registration or by July 1, 2017, whichever is sooner; requiring that pharmacists be registered with the Program by July 1, 2017; altering the mission of the Program; authorizing the Secretary of Health and Mental Hygiene to identify and publish a list of monitored prescription drugs that have low potential for abuse; etc.	Delegate Barron	Returned Passed Meetings to combine language with Gov's Bill SB537—pg 7 lines 14–18 pharmacist language removed.
HB1241 Pharmacy Benefits Managers—Contracts With and Reimbursement of Pharmacists Requiring each initial and renewal contract between a pharmacy benefits manager and a contracted pharmacy to include the sources used to determine maximum allowable cost pricing; requiring a pharmacy benefits manager to update its pricing information at specified intervals and for a specified purpose; specifying the format in which pricing updates must be provided by a pharmacy benefits manager to a contracted pharmacy; etc.	Delegate Kipke	Unfavorable
HB1242 Pharmacy Benefits Managers—Reimbursement and Pharmacy Choice Prohibiting a pharmacy benefits manager from reimbursing a pharmacy or pharmacist for a pharmaceutical product or pharmacist service in a specified amount; authorizing a pharmacy or pharmacist to decline to provide a pharmaceutical product or pharmacist service to an individual or pharmacy benefits manager under specified circumstances; prohibiting a pharmacy benefits manager or health benefit plan from imposing specified conditions on an individual or covered entity under specified circumstances; etc.	Delegate Kipke	Unfavorable
HB1347 Maryland Medical Assistance Program—Managed Care Organizations—Disenrollment Authorizing a Maryland Medical Assistance Program recipient, under specified circumstances, to disenroll from a managed care organization to maintain continuity of care with a pharmacy provider; requiring the Department of Health and Mental Hygiene to provide timely notification to the affected managed care organization of an enrollee's intention to disenroll under specified provisions of the Act; etc.	Delegate Kipke	Unfavorable

Continued on page 10

Title	Primary Sponsor	Status
HB1383 (SB1018) **Health Insurance–Specialty Drugs—Participating Pharmacies** Altering the conditions under which insurers, nonprofit health service plans, or health maintenance organizations may require a covered specialty drug to be obtained through a pharmacy participating in the provider network of the insurer, nonprofit health service plan, or health maintenance organization; altering the definition of "specialty drug"; etc.	Delegate Kipke	Unfavorable
HB0752 (SB0647) **Physicians—Prescriptions Written by Physician Assistants—Preparing and Dispensing** Providing that specified provisions of law do not prohibit a licensed physician from personally preparing and dispensing a prescription written by a physician assistant in accordance with a specified delegation agreement if the physician complies with specified requirements.	Delegate Cullison	Returned Passed
HB0826 Prescription Drug Repository Program—Repository Inventory Requirement —Revision Requiring a repository that participates in the Prescription Drug Repository Program to maintain a separate inventory of donated prescription drugs and medical supplies that the repository intends to dispense under a specified provision of law, instead of a separate inventory of all donated prescription drugs.	Delegate Adams	Unfavorable
SB0091 Public HealthState—Identified HIV Priorities Requiring rebates received by the Department of Health and Mental Hygiene from the Maryland AIDS Drug Assistance Program as a result of State General Fund expenditures to be distributed to a specified special nonlapsing fund and used only to fund State-identified priorities for HIV prevention, surveillance, and care; requiring the Secretary of Health and Mental Hygiene to adopt regulations establishing, as appropriate, income and other eligibility criteria for the receipt of specified HIV prevention and care services.	Chair, Finance Committee	Approved by the Governor— Chapter 46
SB0806 State Board of Physicians—Naturopathic Doctors—Establishment of Naturopathic Doctors Formulary Council and Naturopathic Formulary Establishing a Naturopathic Doctors Formulary Council within the State Board of Physicians; providing for the membership, terms, compensation, chair, and staff for the Council; requiring the Council to develop and recommend to the Board a specified formulary, provide specified reviews of the formulary, and make specified recommendations to the Board; requiring the Board to adopt a specified formulary; etc.	Senator Pugh	Returned Passed
HB0056 (SB0063) **Investigational Drugs, Biological Products, and Devices—Right to Try Act** Authorizing a manufacturer of an investigational drug, biological product, or device to make available the investigational drug, biological product, or device to eligible patients; specifying the manner in which a specified drug, product, or device may be provided to eligible patients; prohibiting a health occupations board from taking specified action against a health care provider's license on a specified basis; establishing that this Act does not create a specified cause of action; etc.	Delegate Young, K.	Unfavorable
HB0091 (SB0442) **General Provisions—Commemorative Days—National Healthcare Decisions Day** Requiring the Governor annually to proclaim April 16 as National Healthcare Decisions Day.	Delegate Morhaim	Returned Passed
SB0418 (HB0404) **Richard E. Israel and Roger "Pip" Moyer End-of-Life Option Act—** Authorizing an individual to request aid in dying by making specified requests; prohibiting another individual from requesting aid in dying on behalf of an individual; requiring a written request for aid in dying to meet specified requirements; establishing requirements for witnesses to a written request for aid in dying; requiring a written request for aid in dying to be in a specified form; requiring an attending physician who receives a written request for aid in dying to make a specified determination; etc.	Senator Young	Unfavorable Withdrawn

Editorial

University of Maryland School of Pharmacy Celebrates 175th Anniversary

By: Malissa Carroll

A reflection on how the School continues to be one of the leaders in pharmacy education, scientific discovery, patient care, and community engagement across the state of Maryland and beyond.

Visiting the University of Maryland School of Pharmacy today, one cannot help but notice some bold changes in the décor both inside and around Pharmacy Hall. New signage along Pine and Fayette Streets, as well as colorful wrappings on the poles, stairs, and elevators in the Ellen H. Yankellow Grand Atrium signify the commemoration of an important milestone in the School's history. It is the School's 175th anniversary, and throughout 2016, faculty, staff, students, alumni, and friends are celebrating its nearly two centuries of leadership in pharmacy education, scientific discovery, patient care, and community engagement across the state of Maryland and beyond.

Maryland College of Pharmacy
Building erected in 1886

"This remarkable milestone in the School of Pharmacy's history could not have come at a more opportune time, as health care professionals and policymakers alike begin to recognize the essential role that pharmacists play in the nation's health care delivery system," says Jay A. Perman, MD, president of the University of Maryland, Baltimore (UMB). "With cutting-edge practice and research initiatives in the fields of drug discovery, drug development, and drug delivery, the School makes a tremendous impact not only on the pharmacy profession, but also on patients' lives. It is what the School has done for 175 extraordinary years, and what I hope it will continue to do for many more years."

From Humble Beginnings

Established in 1841, the School of Pharmacy was first known as the Maryland College of Pharmacy. It was initially chartered by the Maryland General Assembly in response to concerns from practicing apothecaries about the need for more educated and better trained pharmacists and pharmaceutical assistants to address the increasing number of medicines available to treat different illnesses. Before gaining recognition as a thriving center for professional and graduate education, pharmaceutical care, research, and community service, the School's first class included only six students and was held in a single room at the corner of Gay and Baltimore Streets.

Now ranked as one of the top ten schools of pharmacy in the United States, the School boasts more than 90 faculty, 300 staff, 700 students across its Doctor of Pharmacy (PharmD) and graduate programs, and 5,500 living alumni.

Continued on page 17

Cover Story

This interview first appeared in Georgia Pharmacy *magazine.*

Provider Status

We talk a lot about the idea of pharmacists having "provider status." But what exactly does that mean? Georgia Pharmacy Association CEO Scott Brunner sat down with Krystalyn Weaver, PharmD, the vice president of policy and operations for the National Alliance of State Pharmacy Associations, to talk about that phrase — why provider status is important, what it means and why we're working so hard to achieve it locally and nationwide.

Krystalyn Weaver, PharmD

Across practice settings, provider status is seen as the great brass ring for pharmacists. So let's start by defining the term: What is provider status, and why do we need it?

Today the federal government does not recognize pharmacists as medical "providers" — specifically in Part B of the Social Security Act. That means Medicare beneficiaries aren't able to access pharmacists' patient-care services such as diabetes management, smoking cessation assistance, and even simple wellness visits through their Medicare benefits.

Hence our goal of attaining federal "provider status." A major step of that would be passage of the Pharmacy and Medically Underserved Areas Enhancement Act, aka H.R. 592 or S.314. It would allow Medicare to pay for pharmacists' services in medically-underserved areas.

But if you dig into the "why" of that objective, it's more than just about pharmacists. It's about the fact that patients benefit from the valuable services pharmacists can provide. We know that when pharmacists are on the healthcare team, outcomes improve and costs go down.

To sum it up, the goal is to ensure that patients' have access to pharmacists' brains — not just the products we dispense.

Back to the term *provider status.* Medicare access is a major step, but it's only the *first* step. The reality is that we need to approach ensuring patient access to pharmacists' services from more than one angle. Though Medicare patients make up a huge population of those who would benefit from pharmacist's knowledge and skills, there are many other patients who do not have Medicare coverage.

So "provider status" is broader. It encompasses *any* effort to get patients access to these services, which makes the meaning of that term somewhat complicated.

Add to that the fact that not every pharmacist *wants* to provide those services. Often when I'm talking about integrating more patient-care services into our practices, I get the inevitable comment: "I'm too busy in the pharmacy as it is. There is no way I can add even *more* activities to my day-to-day operations and still get prescriptions filled."

As a practicing community pharmacist myself (although it's only moonlighting), I can relate. Any pharmacist (or consumer for that matter) knows how busy a community pharmacy can be. It is, in fact, difficult to add to that workload in the world we live in now.

But that's the key phrase: *in the world we live in now.* It doesn't have to be this way.

I challenge my peers not to think of the current practice environment. When we're talking about broadening pharmacists' services, think of the future. Remember that the reason we aren't already doing this is because our payment system is broken — it doesn't recognize the value pharmacists are capable of providing. A core premise of the provider status push is that we have to change our business model. We need to *change* the practice environment and make it feasible for our services to be delivered effectively.

We are talking about overhauling our workflow so patient-care services become a focus, not an add-on. And yes, we're talking about new streams of revenue.

I would also argue that considering the ever increasing pressures to decrease what Americans pay for

prescription drugs, that a change in our business model is likely essential for pharmacies to survive. Any pharmacy owner can attest to the fact that margins are decreasing. In order to keep pharmacist jobs viable, we need to leverage our most valuable asset: our ability to optimize medication regimens, assist patients with disease management and prevention, and decrease overall health care costs — not just get the right drug to the right patient at the right time (although that will always be important).

If the case is so strong, what's keeping Congress?

That's a great question, but it assumes that policy decisions are always made with 100 percent reliance on facts and data. The reality is that national policy is influenced by political pressures. And one of the biggest political pressures we're facing today is our national debt and the ever ballooning costs of entitlement programs. Adding pharmacists' services to Medicare benefits will come at an added cost to the program, at least initially.

So rather than reflecting on why it hasn't happened yet, I like to focus on why now is a good time. There has never before been more of an awareness on health policy in the larger policy environment. Policy makers are realizing that saving money is more than simply cutting costs — it's also critical to get the most value.

Pharmacists are pros at keeping people healthy and maximizing the utility of a critical healthcare resource: medications. We have plenty of data to show that.
More people are realizing this, so not only do we have unprecedented collaboration among pharmacy associations, wholesalers, and national pharmacy chains, we are now seeing support from many outside organizations such as the Centers for Disease Control and Prevention, the National Governors Association, the Office of the Surgeon General, and others.

Okay, so Congress is concerned about the price tag. I get that. Isn't there research, though, to demonstrate that the long-term savings from compensating pharmacists as providers is greater than the short-term costs? I can imagine healthier patients and reduced hospital admissions could save Medicaid and Medicare some real money.

Absolutely, there are *plenty* of data to show that pharmacists can save payers on the overall cost of healthcare in both the short and long term. There are hard data showing that within one year, simply paying pharmacists to provide modest MTM services for Medicaid patients delivered a 4 to 1 return on investment. And data for the long term is even stronger — an average ROI as high as 12 to 1.

Unfortunately, the way new federal bills are analyzed doesn't account for these savings. The Congressional Budget Office assigns a "score" to bills that estimates the cost of the bill to the federal budget over the next 10 years. *But that score doesn't take into account cost savings* — which doesn't help our cause one bit. We've heard that this process may be loosening a bit but the score of the federal bill will continue to be a challenge, especially in an election year.

I challenge my peers not to think of the current practice environment. When we're talking about broadening pharmacists' services, think of the future. Remember that the reason we aren't already doing this is because our payment system is broken — it doesn't recognize the value pharmacists are capable of providing. A core premise of the provider status. push is that we have to change our business model. We need to *change* the practice environment and make it feasible for our services to be delivered effectively.

You've mentioned that Congress would need to enact provider status at the federal level. But what about at the state level? Is there any benefit to asking the legislature to grant pharmacists provider status on a state level? What would state provider status look like?

Absolutely, there is a lot states can do to ensure patients access to and coverage for pharmacists' patient care services (which is really what we mean by "provider status," remember). Unfortunately, it isn't as simple as a state legislature granting provider status. The state environment is different than the federal one. At the federal level, a somewhat simple change of definition in law results in a massive change in the payment structure for MANY patients across the country. At the state level this almost always isn't the case.

There are often several places in state law and regulation where the term "provider status" is defined, each with a different degree of impact on patient access to pharmacists' services. They may be important in their own way but are very unlikely to be the broader solution that a federal change would be.

Additionally, it's at the state level where scope of practice is defined, and that's an essential factor in pharmacists' ability to provide the care they want to provide. In recent years, states have made improvements to laws regulating pharmacists: broadening immunization and collaborative practice agreements, allowing pharmacists to prescribe

travel medication, and promoting access to public health services through pharmacies, such as smoking cessation products and hormonal contraceptives.

Finally, states can influence local payers including Medicaid, state employee plans, and private payers through legislative or regulatory action, or by simply working with those payers directly and sharing the business case with them.

So are we talking about expanding pharmacists' scope of practice? Providing services under collaborative practice agreements with physicians? Or simply doing stuff pharmacists can already do but currently can't be compensated for?

All of the above. As we discussed before, state provider status efforts often include work to align pharmacists' scope of practice with their clinical ability — so patients aren't missing out on pharmacists' care because of outdated laws. Collaborative practice agreements can allow for increased collaboration and efficiencies in care delivery — unless the state laws and regulations are so restrictive that entering into an agreement becomes a burden.

And finally there is "stuff" pharmacists can already do and *already are doing* that they aren't being compensated for. It won't be as easy as just submitting a quick claim for services; we'll need to comply with the rules and regulations other providers comply with now — including credentialing, documentation, quality assurance, etc.

How do you think physicians will react to that? Does it change the physician–pharmacist relationship?

The examples we currently have of physician-pharmacist collaborations are relatively few and far between because it requires great creativity to make the relationship financially viable. But when we *are* able to find sustainable revenue streams to take the strain off of the system, physicians often report favorably on working closely with pharmacists. I think physicians and other providers will embrace the presence of pharmacists on the health care team. Let's face it — drugs are complicated and there are plenty of other things doctors, nurses, physician assistants, and nurse practitioners have to focus on. Having a medication expert on their side will make their job that much easier and allow them to provide care to more patients.

How do you see this new paradigm impacting the quality of patient care?

It's been said many times before, but I'll say it again: *When pharmacists are on the team, health outcomes improve and costs go down.* I think it's a given that pharmacists' services can improve quality. The impact pharmacists are already making, even in our broken system, is probably underappreciated. But I think if we align the incentives appropriately — and build an infrastructure that allows pharmacists to access the patient health data they need — the system can be fixed to maximize pharmacists' skills and improve patient care.

Let's talk about compensation. If, as providers, pharmacists could be compensated for a broader range of their services, what does that look like? What are the mechanics of it?

I don't want it to sound like an easy, quick transition. We'll need to adjust workflows, reimagine how we use pharmacy technicians, implement infrastructure changes to allow pharmacists to plug into the information systems hospitals and doctors use, and learn how to do medical billing. And medical billing is VERY different

PROVIDER STATUS IN MARYLAND

Richard DeBenedetto, PharmD, MS, AAHIVP, Chair, Provider Status Working Group, Maryland Pharmacy Coalition

The need for pharmacists to be recognized as providers to provide services that improve outcomes for patients is great. Pharmacists being reimbursed for cognitive patient care services, similar to how other professions are reimbursed, is necessary to place more pharmacists into settings where they are monitoring all aspects of medication use. With small efforts to provide MTM services, we see substantial ROI, the expansion of MTM, disease state management, and other cognitive services. Expanded cost savings are generated and value is placed on pharmacist services where it belongs — on the service and not on the product.

While the federal provider status initiatives are helpful in some respects, they do not help all Maryland patients. The federal law only would apply to Medicare patients in underserved areas; we have many Medicare patients needing pharmacist services outside of the specified areas and there are many patients who are not covered by Medicare.

MARYLAND PHARMACY COALITION (MPC) AND PROVIDER STATUS

In the 2015 legislative session, MPC developed and facilitated passage of two bills signed in to law that advance pharmacists as providers. The first bill allows pharmacists to be able to administer 'self administered' medications. While this sounds like a minor effort, this is not allowed in many states and improves our ability to provide assistance to patients in need. A second bill expanded the scope of Drug Therapy Management Contracts,

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than prescription billing, which is quick, automated and immediately tells you if a claim is covered.

In medical billing, a claim is submitted, but the provider may not know for weeks if it will be paid by the insurer. Copays have to be collected at the time of service but are only estimates of what the patient's cost share is — meaning you have to bill the patient after the fact as well. And if a claim isn't covered, the dispute process can be lengthy and arduous. Obviously all of these challenges have been overcome by our colleagues in other health professions so they're not insurmountable, but they will be big changes for pharmacy.

Sounds like this is an issue pharmacists need to anticipate, so that when it's enacted, our members are ready to take advantage of it on day one. What can pharmacists be doing now to prepare themselves, their practices, and their patients for provider status?

Pharmacists can get themselves ahead of the game by incorporating services into their current business model now. Start small. Consider incorporating medication synchronization into your pharmacy. Incorporate other adherence interventions. Make sure to fulfill all of the Medicare Part D MTM opportunities that come your way. This will help you to get your workflow to a better place and start to change patient perceptions about the level of care pharmacists are capable of providing.

Build relationships in the community. Reach out to local physicians' offices, get to know the care managers in the local hospital and see if you can find a way to help them with medication reconciliation at discharge. Building relationships will also build a referral network. Yes, this will mean business when we are able to bill Medicare for medical services, but it will also mean increased business now. If your local providers see you as the go-to pharmacy for optimal medication management, they will send their patients to you.

Try to understand the quality measurement landscape — and beyond Star Ratings. Physicians, ACOs, medical homes, and hospitals are all held to different quality metrics. Learn what they are, learn what the pressure points are, and think of how pharmacists can help to achieve those metrics. Also, get to know the billing codes that may be available to us through Medicare. These include CPT codes, chronic care management codes, G-Codes and more. The Medicare Learning Network is a great resource. Sign up for their email list and get information sent to you regularly.

also known as collaborative practice agreements. The changes allow for pharmacists to initiate therapy under protocol from physicians and also allow non-physician prescribers to enter into agreements with pharmacists.

Our current efforts are now focused on payment for pharmacist services. We are currently allowed to do many patient care activities, but have few funding mechanisms for this care. Through careful examination of several insurance benefits contracts and the law, we are researching areas where expansion of payment may be contractually contained or legally required in Maryland. We are also looking to work with Medicaid and other insurance providers to seek ways to include pharmacists in the listing of providers who can bill for services.

Finally, we are working to change the status quo by educating other professions about the benefits of pharmacists in the direct care of their patients. Not only are there cost benefits to the system for reducing patient care expenditures, but other providers can actually earn money by including pharmacists who can bill services on the patient care team.

WHAT CAN YOU DO?

- Urge your elected leaders to support HR 592/S314 Pharmacy and Medically Underserved Areas Enhancement Act
- Provide education to providers on what pharmacists are qualified and able to do for them and their patients
- Engage in formal opportunities to collaborate in the professional setting and improve professional relations with other providers outside the medical setting

Editorial

The Role of Ethics in Pharmacy

By: Dixie Leikach, RPh, MBA, FACA

President and CEO of PEER (Pharmacy Ethics, Education, and Resources)

Pharmacy is an honorable profession. Pharmacists, student pharmacists, and pharmacy technicians work hard and spend their days in stressful environments, yet make a difference in patients' lives. Pharmacy technicians are on the front lines and are a pharmacists' eyes and ears. Student pharmacists study hard and dedicate the most time of any healthcare professional to the mastery of medications. While this article focuses on pharmacists and their role in making ethical decisions, this topic is relevant to all pharmacy professionals regardless of role. Ultimately, running a pharmacy is a team effort, and the team must play by the same set of rules to maximize efficiency and effectiveness.

There are core assumptions that those that decide on pharmacy as a profession are knowledgeable, educated, and ethical, and that these individuals want what is best for the patient at all times. Ethics plays a large part in the public's perception of pharmacists and patient safety.[1] However, little information on pharmacy-specific ethics exists, and few educational sessions are available to improve pharmacist's knowledge. The more discussions pharmacists have on ethics, the better pharmacists can serve their patients.

Autonomy, beneficence, nonmaleficence, and justice are the four leading healthcare ethical principles.[2] Autonomy is the principle that patients have the right to make their healthcare decisions, and the job of the healthcare professional is to ensure the patient has all of the necessary information to make their decisions. The healthcare professional must respect the decision of the patient, even if the decision doesn't perceive the patient's best interest. Beneficence is the principle that healthcare professionals must strive to do the best for every patient in every unique situation. Nonmaleficence is the principle of "first, do no harm" and is the principle that most healthcare professionals recognize and follow.[2] The last principle, justice, highlights that healthcare professionals must be fair and consistent in treatment decisions and allocations of resources for every patient. In making a sound ethical decision of justice, healthcare professionals must be able to justify their actions.[3]

Although pharmacy is a healthcare profession, in many practice settings, it is also a business. Therefore, the principles of business ethics must also be considered. Healthcare is changing and payment models are shifting. Pharmacists must comply with both business and healthcare ethical principles when making decisions in their workplace in order to keep the patient's best interests at the forefront. Many principles are considered business ethics, but there are common themes among all such as, trustworthiness, responsibility, citizenship, fairness, caring, and respect. Integrating all of these principles into each decision can be difficult, but one easy way to determine if a business decision is ethical is by considering whether it would hold up under the scrutiny of a regulatory review or audit.

Thorough knowledge and consideration of pharmacy regulations is a prerequisite to making sound decisions. This is necessary not only because adherence is mandated, but also because many of the regulations resulted from high-profile situations where the actions of a few pharmacists purposefully or accidentally ignoring sound ethics resulted in significant patient harm and great public concern. Consequently, laws were then changed to prevent a recurrence. Two cases in particular have had lasting effects on our profession, and it is important for all members of the pharmacy team to reflect on them.

One particular law that dictates most of the pharmacy profession today is the Federal Food, Drug, and Cosmetic Act of 1938.[4] This law was the result of the sulfanilamide tragedy, and with its many updates it still stands today. The pharmacist that concocted the poisonous substance containing diethylene glycol, an antifreeze agent, to hide the flavor of the bitter medication may or may not have known that there was a risk with the formula used. Whether the pharmacist knew beforehand this was a potent poison was never determined, but regardless of his knowledge, ultimately over 100 people died and countless more sustained serious illness. As healthcare professionals, the need to embrace change and look for new ways of healing are necessary. However, healthcare professionals always need to consider the worst case scenario and make sure the mainstay principle of ethics is being

honored: nonmaleficence, first do no harm.

More recently, the Drug Quality and Security Act of 2013 is the result of the New England Compounding Center tragedy, where one pharmacy caused 64 deaths and illness in over 800 patients due to poor practice and alleged illegal activity.[5] Violations of many ethical principles caused patient harm and a tremendous change in the profession. As seen in both examples, the breach of ethics can irrevocably change lives.

Ethics plays a large role in healthcare professionals' everyday lives. Pharmacists that consider ethics in their daily practice are more likely to improve patient safety and their standard of practice. Ethical decisions are not always easy and sometimes contradict each other. However, it is crucial to continue to increase awareness and education on the topic of ethics and how it plays an important role in pharmacy in order to better serve patients.

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University of Maryland School of Pharmacy Celebrates 175th Anniversary *continued from page 11*

"All alumni should be proud to be part of the School's amazing 175-year legacy," says Sharon Park, PharmD '04, president of the School's Alumni Association. "It is important to remember, however, that it is not only the number that is important, but also the excellence and dedication of the School's faculty, staff, students, and alumni that has persevered over all this time."

A Grand Birthday Celebration

To formally kick-off the School's year-long anniversary celebration, Natalie D. Eddington, PhD, FCP, FAAPS, dean and professor of the School, hosted a birthday celebration for faculty, staff, students, and alumni on Feb. 10. The celebration, which featured birthday cakes decorated with photos of the five different buildings in which the School has been housed throughout the years, offered an opportunity to reflect on the School's history and called on attendees to look beyond the School to how the advances being achieved within its walls could make the greatest impact on the local community.

"The one word that comes to mind when I think about the School on the occasion of its 175th anniversary is 'community,'" says Eddington. "We are a strong, thriving community of scholars, practitioners, researchers, students, and staff. As we kick off the many celebrations that will mark this milestone year, my challenge to all of you is to think about the community beyond the walls of Pharmacy Hall. I want all of us to work together to focus on service during this 175th anniversary, and to build upon the great work that our faculty, staff, and students already do with many community groups."

Beyond the Walls of Pharmacy Hall

From offering tutoring services for middle and high school students to conducting research that leads to the development of new medications, there is a lot of great work being done by faculty and students alike to help enhance the local community. Faculty in the School's Department of Pharmacy Practice and Science partner with more than 200 community pharmacies, hospitals, nursing homes, and other agencies to provide services to residents and practitioners across the state of Maryland and beyond. The Patient-Centered Involvement in Evaluating the Effectiveness of Treatments (PATIENTS) program led by C. Daniel Mullins, PhD, professor and chair of the Department of Pharmaceutical Health Services Research at the School, has also been recognized for its groundbreaking work to empower patients to propose questions about their health care and participate in research studies designed to help answer those questions.

However, as Eddington notes, there is still much work to be done.

"Baltimore City is much different today than it was in 1841," adds Eddington. "It is a vibrant, dynamic community, but it is also in need of our assistance. Many of our neighbors lack access to basic goods and services, as well as to health care. Faculty, staff, students, and alumni at the School have a multitude of expertise and the ability to help move our city forward. We have the manpower, the drive, and the heart to be more involved and to make more of a difference."

Continuing Ed

Take Each Pill with a Grain of Salt:

A Review of Abuse-Deterrent Opioid Formulations and Place in Therapy

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Opioids have been used for their analgesic and sedative properties throughout history; references to medical use of the opium poppy plant can be found dating back to ancient civilizations in Mesopotamia as early as 3000 B.C.[1] With the therapeutic use of opium came struggles with abuse and addiction, prompting the search for safer analgesic agents. Morphine (named for Morpheus, the god of dreams) was isolated in 1806, but was quickly found to have a similar potential for abuse as opium. When heroin was synthesized almost a century later, it was initially touted as a potent analgesic and abuse-free opioid.[2] Needless to say, such claims of low potential for abuse and addiction from morphine and heroin have been thoroughly discredited.

Despite significant advancements in drug development in other therapeutic areas, opioids remain the gold standard for treatment of severe acute and cancer-related pain. The use of opioids for chronic non-cancer pain is more controversial. It is estimated that 90–95% of prescriptions for long-term opioid therapy are for non-cancer indications.[3] Opioid prescribing increased significantly since the early 1990s when quality initiatives, such as 'Pain as the 5th Vital Sign' through the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Veterans Health Administration sought to address inadequately treated pain through the promotion of consistent standards for monitoring and treating pain.[4] Unfortunately, increases in opioid prescribing are mirrored in trends in abuse and overdose deaths and have led to an opioid epidemic in the United States.

Learning Objectives

After completing this activity the participant will be able to:

1. Describe trends in opioid abuse and overdose in the United States.
2. List the seven types of abuse-deterrent formulations as defined by the FDA.
3. Describe the abuse-deterrent properties of commercially available products according to the FDA guidance.
4. Select an appropriate candidate for treatment with an abuse-deterrent opioid formulation within a patient case study.

Key Words

- Abuse deterrence
- Opioids
- Drug formulation
- Pain management

The Opioid Epidemic

The sale of prescription analgesics has quadrupled in the United States since 1999. Likewise, the incidence of opioid-related overdose deaths has quadrupled in the same time frame, and more than sixty percent of drug overdose deaths involve an opioid.[5] The agents most commonly implicated in prescription opioid overdose deaths are methadone, oxycodone, and hydrocodone.[6] It should be noted that 73 to 80 percent of methadone overdoses have been classified as unintentional, and the absolute number of overdose deaths involving methadone was less than those involving cocaine, oxycodone, hydrocodone, and fentanyl.[7]

The rate of heroin abuse has also increased substantially since 2006, and the rate of related overdose deaths has more than tripled since 2010.[8] Heroin use is increasing in populations with historically low rates of abuse including women, the privately insured, and those with higher incomes. Prescription medications may be perceived as safer than illicit substances, however addiction to opioid analgesics has been cited as the strongest risk factor for heroin addiction. Individuals who are addicted to opioids are forty times more likely to be addicted to heroin compared to fifteen times more likely if addicted to cocaine, and three times more likely if addicted to marijuana.[9,10] While inadequately treated pain was a concern in the early 1990s, the inextricable relationship between prescription opioids, and prescription and non-prescription opioid abuse, addiction, and overdose deaths is a national priority and has led to the recent implementation of initiatives at local, state, and federal levels.[8]

Combating Opioid Abuse

Many strategies aim to reduce access to opioids for illegitimate or non-medical uses. These include state prescription drug monitoring programs, educational programs for healthcare professionals and the public, overdose prevention measures with opioid antagonists such as naloxone, and punitive legislation.[10,11] These tactics do not alter the abuse potential of opioids, and critics have voiced concern that stringent regulation of prescribing practices may limit access to appropriate therapy for patients with legitimate pain. Abuse-deterrent formulations are a newer tactic employed by drug manufacturers to make the dosage form difficult to manipulate for non-medical purposes. This is differentiated from tamper-resistance, which typically refers to packaging requirements for a medication.

The most common route of administration implicated in opioid abuse is oral ingestion of an intact or compromised dosage form, but can also involve inhalation or injection. Dosage forms can be crushed, chewed, ground, pulverized or extracted to make the medication easier to swallow or allow for an unintended route of administration. Physical alteration decreases the time to maximum concentration (T_{max}) and increases the maximum concentration (C_{max}) achieved to enhance euphoric effects of the opioid. Many of the commercially available abuse-deterrent opioids make physical alteration difficult and thwart this dose-dumping effect. The U.S. Food and Drug Administration (FDA) released a draft guidance report for pharmaceutical industry on abuse-deterrent opioids in 2013 and final guidance in 2015. The intent of the guidance is to facilitate the development of safer, abuse-deterrent products by providing non-binding standards for abuse-deterrence studies, product formulations, evaluation, and labeling.

Sidebar Case

Prescribing Considerations for Abuse-Deterrent Opioids

Henry, a 35 year-old man, was referred to a pain clinic for chronic lower back pain secondary to a motor vehicle accident. Henry's primary care physician referred him to the clinic after multiple early refill requests for opioids. His current analgesic regimen consists of acetaminophen 650 mg by mouth every 4 hours as needed, MS Contin® (morphine extended release) 15 mg by mouth every 8 hours, and oxycodone 5 mg by mouth every 4 hours as needed. He did not complete recommended physical therapy because he said "it didn't do any stinking good" and high co-pays. Henry is an active smoker (1 pack per day) and has a remote history of cocaine use ten years prior. The patient is 5'10" and weighs 280 pounds; when asked he says "I'm a couch potato and proud of it." When asked about his goals for the treatment plan, Henry states that he would like to increase the dose of his MS Contin® and breakthrough oxycodone so as to be able to return to his job as an accountant and play with his two young children. He is concerned about switching to one of those "new, fancy drugs" due to high costs.

Is this patient at risk for opioid abuse?

Patients should be screened for risk of opioid abusive drug-related behaviors using a validated tool during initial assessment. Risk factors that have been determined to be clinically significant include a family or personal history of substance abuse with alcohol, illegal drugs, or prescription drugs, age between 16 to 45 years, history of pre-adolescent sexual abuse, concurrent psychological disease, and male gender.[24] Henry has multiple "red flags" — he did not follow the complete plan

Potential formulations of abuse-deterrent opioids have been broadly defined within seven categories and are summarized in Table 1.[12]

In order to meet the labeling requirements set forth in the guidance, a medication must demonstrate safety and efficacy in pre- and post-market studies. Category 1 studies evaluate in vitro manipulation and extraction to assess the ease with which the abuse-deterrent properties can be defeated or compromised. Category 2 studies compare the pharmacokinetic profile of manipulated and intact formulations against comparator formulations through one or more route of administration. Category 3 studies are referred to as drug-liking studies and evaluate how probable it is that the formulation will be attractive to abusers. Category 4 post-market studies determine if the formulation resulted in a meaningful reduction in abuse, misuse, addiction, overdose, and death.[12] Studies should assess known or anticipated routes of abuse that are specific to that opioid. By limiting one form of abuse, it is critical that the product does not encourage an alternative, potentially more dangerous route of abuse, such as intravenous injection of an opioid following reformulation to prevent crushing and snorting. Many of the abuse-deterrent products currently on the market target multiple potential routes of administration for this reason.

Abuse Deterrent Opioids

Three products have received FDA approval for abuse-deterrent labeling in the United States. Oxycodone is an opioid that has been widely abused, particularly the extended release formulation OxyContin®. This was the first opioid to be reformulated with abuse-deterrent properties in 2010 and received FDA approval for abuse-deterrent labeling in 2013. OxyContin® utilizes proprietary INTAC® technology that is resistant to crushing, breaking, and dissolution and is categorized as a physical/chemical barrier. If submerged in an aqueous environment, the tablet forms a viscous hydrogel that resists passage through a needle and cannot easily be snorted.[13] Early category 4 post-marketing studies demonstrated a 32–33 percent reduction in abuse, a 15 percent reduction in overdoses, and a 22 percent reduction in street price.[14,15]

Hysingla®, extended release hydrocodone, received approval for abuse-deterrent labeling in 2014 and is classified as a physical/chemical barrier. This agent utilizes a proprietary RESITEC® formulation that confers tablet hardness to resist crushing or chewing, and forms a viscous substance if dissolved in aqueous solutions to deter snorting or injecting.[16]

Embeda® is an agonist/antagonist formulation that was approved in 2014. It contains a combination of extended release morphine and the opioid antagonist naltrexone, which is sequestered and has no effect if taken as directed. The naltrexone is fully released if the dosage form is crushed, chewed, or dissolved in a solvent and may precipitate withdrawal in opioid-dependent patients.[17]

Other commercially available opioids have physical/chemical barriers against abuse, but have not received FDA approval for abuse-deterrent labeling. Zohydro® is extended release hydrocodone formulated with BeadTek®, an excipient that immediately forms a viscous gel if the tablet is crushed and dissolved to deter snorting or injecting.18 Exalgo® is an extended release product containing hydromorphone. Exalgo® is formulated with an osmotic delivery system that is resistant to crushing and extraction, and releases the hydromorphone at a

of care (physical therapy), history of smoking and cocaine use, and multiple requests for early refills.

What observed behaviors might be of concern for opioid abuse or misuse?

Aberrant behavior describes patient actions that are inconsistent with the prescribed treatment plan. These range from mild behaviors, such as using pain medication to treat other symptoms such as anxiety, to more severe behaviors such as crushing and snorting oral medications to achieve more rapid onset. Drug-seeking behavior is often a red flag to prescribers, but behaviors may overlap with signs of untreated pain: frequent emergency room visits, preoccupation with obtaining pain relief, and requesting specific analgesics by name.[25] Henry's physician states the patient is consistently requesting early refills of opioids.

What factors should be considered prior to recommending an abuse-deterrent opioid?

First, determine if the patient is an appropriate candidate for opioid analgesia based on the pain syndrome. For example, low back pain is a chronic condition where opioids are usually NOT recommended. Henry should follow the plan of care for drug and non-drug therapy, and life style modification is likely an important part of his treatment plan (lose weight, exercise). Also, neuropathic pain is generally a considerable part of low back pain; Henry would likely benefit from an adjunctive analgesic such as gabapentin, pregabalin, a tricyclic antidepressants, or duloxetine.

Assuming opioid therapy is appropriate, it is important to obtain a thorough history and conduct a validated risk assessment to identify patients who are actively abusing or at high risk for abusing opioids, and by what route. Other factors to consider include insurance formularies and the patient's ability to afford the medication, if the abuse-deterrent formulation targets anticipated routes of abuse, and if the patient is able to ingest the intact dosage form.

controlled rate over 24 hours.[19] New abuse-deterrent opioids are currently under development, some of which feature aversion technology with substances like niacin that would cause nasal irritation and flushing if the tablet were crushed and snorted.

Conclusion

The number of abuse-deterrent opioids that have been brought to market in recent years is reflective of a collective commitment to addressing the national opioid epidemic. Despite this, place in therapy for these products remains unclear due to several factors. The rate of opioid-related deaths has continued to increase despite the introduction of abuse-deterrent formulations.[20] A study of 11,000 drug users at 150 treatment centers across the U.S. revealed that 25 percent continued to abuse OxyContin® even though they found the new abuse-deterrent formulation to be less attractive.[21] Perhaps a more sobering trend is an increase in heroin abuse by almost 100 percent which has coincided with a 47.4 percent reduction in OxyContin® abuse. This is largely due to reduced availability of the old OxyContin® formulation that lacked barriers to abuse, and a lower relative cost of heroin compared to OxyContin®.[22] Cost is a limiting factor for many patients, as generic products are more favorably priced and the abuse-deterrent products are currently brand-only. Coverage for OxyContin® under Medicare Part D actually decreased from 61 percent to 33 percent from 2012 to 2015 while the generic immediate-release formulation of oxycodone, which lacks abuse-deterrent properties, was fully covered.[23] Price competition may reduce prices as more abuse-deterrent formulations are approved however high co-pays are a barrier for many patients.

Regulations and medication-based technology must be capable of evolving with rapidly changing trends to continue to provide a meaningful impact in abuse. Users who are determined to obtain euphoric effects can easily find tips and how-to videos on web-based forums with detailed instructions on defeating abuse-deterrent properties. Although the new formulations prevent alteration of the dosage form, they do not prohibit patients from ingesting a higher quantity than directed to achieve desired effects and do not protect against the most common form of ingestion in opioid overdoses — the oral route.

Most importantly, reformulating opioids to reduce abuse does not address underlying issues with addiction or prevent patients from becoming addicted. The abuse-deterrent formulations may be beneficial in a subset of patients; particularly those identified as high risk for abuse based on validated screening tools. Patients who abuse opioids by inhalation or injection may also be appropriate candidates for abuse-deterrent formulations, but must be monitored closely to ensure they are not shifting to heroin abuse. Patients may even request these products if they are concerned about diversion in the home from family, friends, or caregivers. Crush-resistant opioids are not appropriate for all patients, particularly those with enteral feeding tubes. It is imperative that healthcare providers remain aware of the distinction between abuse-deterrence and abuse-proof to avoid developing a false sense of security. The prescribing of abuse-deterrent formulations does not preclude completing initial and repeat risk assessments, performing appropriate monitoring and follow-up, or using good clinical judgment. Opioid abuse is a complex and deep-rooted problem that requires a multimodal approach in order to affect meaningful change.

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Table: Abuse-Deterrent Formulations (12)

FORMULATION	DESCRIPTION	EXAMPLES
Physical/ chemical barriers	Drug release limited following manipulation, or physical form is changed to make it more difficult to abuse	• Physical barriers prevent chewing, crushing, cutting, grating, or grinding • Chemical barriers resist opioid extraction with water, alcohol, or organic solvents
Agonist/ antagonist combinations	Interfere with, reduce, or defeat euphoria associated with abuse	• Opioid antagonist, such as naloxone, may be sequestered so that it is only released upon product manipulation
Aversion	Substance added to opioid to produce unpleasant effects if the dosage form is manipulated or used at a higher dose than directed	• Irritation to nasal mucosa if manipulated product were snorted
Delivery system	Drug-release designs or delivery methods that offer resistance to abuse	• Depot injections and implants that are difficult to manipulate
New molecular entities and pro-drugs	Could contain a chemical barrier to *in vitro* conversion to active opioid to deter abuse	• Need for enzymatic activation • Different receptor binding profiles • Slower penetration into the central nervous system • Other novel effects
Combination	Two or more formulations combined to deter abuse	• Combination of physical barrier and aversion
Novel approaches	Novel approaches or technologies not captured in previous categories	

CONTINUING EDUCATION QUIZ

PharmCon is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. A continuing education credit will be awarded within six to eight weeks.

Program Release Date: 05/01/16

Program Expiration Date: 05/01/19

This program provides for 1.0 contact hour (0.1) of continuing education credit. Universal Activity Number (UAN) 0798-9999-16-054-H04-P

The authors have no financial disclosures to report.

This program is Knowledge Based — acquiring factual knowledge that is based on evidence as accepted in the literature by the health care professionals.

Directions for taking this issue's quiz:

This issue's quiz on **Take Each Pill with a Grain of Salt: A Renew of Abuse-Deterrent Opiod Formulations and Place in Therapy** can be found online at www.PharmCon.com.

(1) Click on "Obtain Your Statement of CE Credits for the first time.

(2) Scroll down to Homestudy/ OnDemand CE Credits and select the Quiz you want to take.

(3) Log in using your username (your email address) and Password MPHA123 (case sensitive). Please change your password after logging in to protect your privacy.

(4) Click the Test link to take the quiz.

Note: If this is not the first time you are signing in, just scroll down to Homestudy/ OnDemand CE Credits and select the quiz you want to take.

CE Questions Answers *from page 24*

1) B; 2) C; 3) A; 4) D; 5) B; 6) A; 7) D; 8) C; 9) B; 10) A

CE Questions

1 Physical barriers against opioid abuse are best described as:

A. Medication formulations that prevent oral ingestions

B. Medication formulations that prevent chewing, crushing, or grinding

C. Chemicals that inactivate the opioid if the product is manipulated

D. Medication formulations that inhibit addictive properties of opioids

2 What category of abuse-deterrent formulation studies evaluates how probable it is that the formulation will be attractive to abusers in drug liking studies

A. Category 1

B. Category 2

C. Category 3

D. Category 4

3 Which of the following was the first opioid to receive FDA approval for abuse-deterrent labeling?

A. OxyContin®

B. Vicodin®

C. Hysingla®

D. Exalgo®

4 The sale of prescription opioids has almost quadrupled in the last decade, while the incidence of _____ has quadrupled as well.

A. Opioid-induced constipation

B. Marijuana abuse

C. Reported pain by patients

D. Opioid-related overdose deaths

5 Embeda® (extended release morphine/naltrexone) utilizes which type of abuse-deterrent formulation?

A. Physical/chemical barrier

B. Agonist/antagonist combination

C. Aversion technology

D. Delivery system

6 The incidence of OxyContin® abuse has decreased substantially since the product was reformulated in 2010. What other trend has coincided with this change?

A. Increase in heroin use

B. Increase in insurance coverage for OxyContin®

C. Decrease in heroin use

D. Decrease in the use of other opioids

7 Which opioids use physical/chemical barriers to prevent abuse?

A. OxyContin

B. Exalgo

C. Embeda

D. A and B

E. All of the above

8 The most common route of administration involved in opioid overdoses:

A. Inhalation

B. Injection

C. Oral

D. Rectal

9 Which of the following is a barrier to the utilization of abuse-deterrent opioid formulations?

A. Lack of guidance from regulatory bodies

B. High cost associated with branded products

C. Lack of prescriber awareness of opioid abuse

D. No opioids have been approved with abuse-deterrent labeling

10 Prescribing abuse-deterrent opioids for patients with pain would be most appropriate based on which of the following characteristics?

A. Patients who report crushing and snorting opioids to achieve faster onset of analgesia

B. Patients with young children in the home

C. Patients with multiple emergency department visits for back pain

D. Patients who require medications be crushed for administration through a PEG tube

Answers on page 23

THANK YOU TO OUR 2016 CORPORATE SPONSORS

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MPhA News

WELCOME NEW MEMBERS

Nina Bemben
Cruzita Bryant
Catherine Chew
Oanh Dang
F. Ray Ford
Christine Guay
John Riley
Masha Tata
Thao Tran

134th Annual Convention

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www.marylandpharmacist.org.

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134th Annual Convention


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Executive Director's Message

APPRECIATION

I express sincere appreciation for all the hard work MPhA volunteers do throughout the year, whether they have an "official" role or not, our volunteers are the fuel that powers MPhA.

If you are not already involved, get involved! It is the best way to get to know your colleagues and engage with people beyond your practice site. There are numerous short-term projects and longer-term leadership opportunities that need your diversity of thought, practice specialty, and experience to make them a success. Many new initiatives come from suggestions made by individual members like you.

The first quarter of 2016 has been quite busy for MPhA!

ADVOCACY

MPhA didn't introduce legislation this year, but we had an engaged legislative session, much of the work involved providing feedback on policy, legislative, and regulatory issues. Thank you to the Advocacy Committee, for providing timely feedback and comments during the session. We made strides in distinguishing MPhA from many other pharmacy interests by providing oral and written testimony; participating in committee working groups; and using our lobbyist to provide follow-up information; and having one-on-one meetings with Delegates.

MPhA connected with the Maryland Congressional Delegation in Washington, DC to educate them about MPhA and to encourage more support of provider status legislation. It was great fun to the attend the APhAPAC reception in Baltimore, which featured Congressman Elijah E. Cummings. He is an advocate for the profession and has a powerful story to tell about his connection to the Maryland pharmacy community.

What's Next?: More meetings with Maryland Congressional delegation. Preparation for the 2017 General Assembly – meetings are already scheduled with General Assembly leadership, Delegates and members of Hogan's administration.

COMMUNICATIONS • OUTREACH

Maryland pharmacists strive to be innovative and respected members of the healthcare team. Part of that effort means we must share with the broader public the great things we are doing. Please continue to share that information with MPhA staff. We have set up a communications model to get press and media communications out quicker. Thank you to the Communications Committee for initiating the Facebook "Likes Campaign," streamlined our social media hashtags, and have other efforts underway to assist with giving the MPhA brand more staying power. Outreach means more targeted connections with prospective members. Kudos to the Membership Committee for developing and welcoming the Federal Pharmacist Network.

What's Next? MPhA Trivia Week; Member Spotlights; and Pharmacist technician programming.

CONTINUING EDUCATION • NETWORKING

There were many activities that provided CE credits, but also gave time for you to meet and connect with old colleagues and build new relationships. In the first quarter, Hoai-An and I traveled to the Eastern Shore, Mid-state, and we are looking forward to visiting our Western Maryland friends at the end of this month. Thank you to the Meeting Planning Committee and others who have facilitated increased CE content for the Mid-Year and Annual Convention. Thank you to the NPN Network for continuing to provide engaging activities that keep new practitioners connected to MPhA. Thank you to our University Partners – APhA's Maryland Pharmacy Night Reception had record attendance and was enjoyed by all!

What's Next?: New Practitioner Network Activities for recent graduates focused on transitioning from student to practicing professional and a new on-staff CE Coordinator.

PROFESSIONAL DEVELOPMENT • PROFESSIONAL RECOGNITION

We have a new Pharmacist Advocate Award, sponsored by Buy-Sell-A-Pharmacy, which recognizes the government affairs activity that has raised pharmacists' awareness of the political process, improved the pharmacy profession and the political process, and/or improved service and education to the patient. The award will be presented at the June Convention.

What's Next?: A medication synchronization and adherence panel discussion bringing together national leaders and Maryland innovators under the ScriptYourFuture Maryland (SYFM) banner. We will also see the launch of a CRISP Portal Accessibility Pilot for Pharmacists. There will also be roll-out of Provider Outreach materials from the Professional Development Committee.

Thank you again to the many MPhA volunteers and to your support network. Your time and commitment is appreciated!

If I don't see you beforehand, I'll see you in the OC!

Aliyah N. Horton, CAE
Executive Director

Do you know a pharmacy technician ready to take on more responsibility in the pharmacy?

The University of Maryland School of Pharmacy's new, online PharmTechX Program will elevate a technician's abilities and improve the efficiency of your pharmacy.

The PharmTechX Program at the University of Maryland School of Pharmacy offers an online, self-paced, and interactive learning environment designed to help advance a technician's skills and education.

At the end of the program, technicians will be able to:

- Assist with medication management and storage
- Conduct medication profile reviews
- Assist with patients' medication histories
- Complete medication checking
- Monitor for medication errors
- Facilitate improvement of the medication process

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Contact us at *pharmtechrx@rx.umaryland.edu* for more information or visit *www.pharmacy.umaryland.edu/PharmTechX.*

134th Annual Convention
The Opening Session Speaker at the 134th Annual Convention presented on Keeping Cool, Calm & Collected when the Pressure is On.

Maryland Pharmacist

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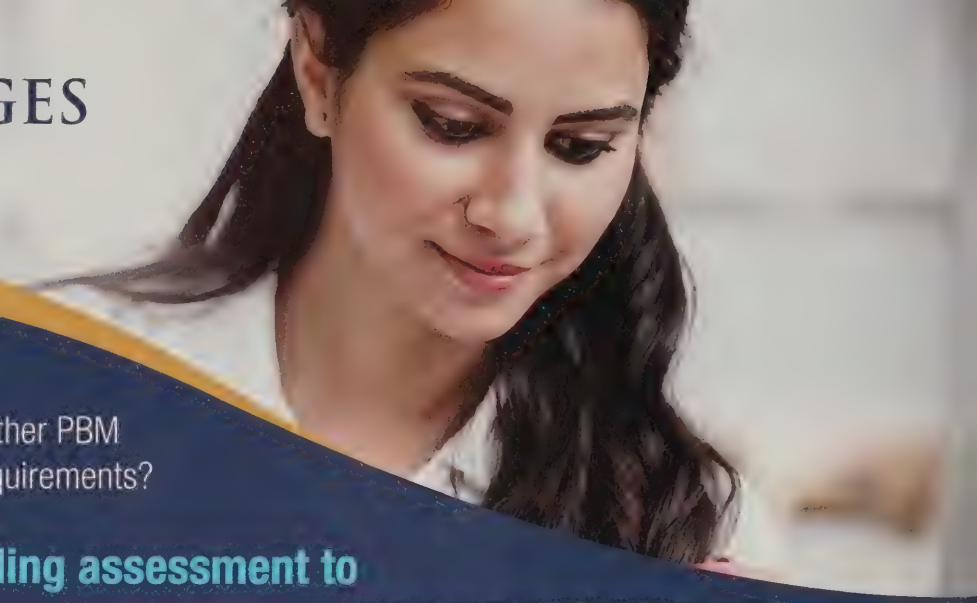

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PHARMACY CREDENTIALING ASSESSMENT

YES NO FWA

- ☐ Are you conducting FWA Prevention training annually?
- ☐ Do you have an "Anti-Kickback" Policy & Procedure (P&P)?
- ☐ Do you have your entire staff completing Conflict of Interest forms annually?

Are you running OIG-GSA-SAM Exclusion Verifications each month on:

- ☐ Employees, Owners and Contractors
- ☐ Business Associates
- ☐ All vendors whose products are billed through Medicare

YES NO HIPAA

- ☐ Do you have a HIPAA P&P manual/program in place?
- ☐ Has your Notice of Privacy Practice been updated since July 1, 2013?
- ☐ Do you maintain a breach assessment when the patient receives another patient's medication?

YES NO PATIENT SAFETY

- ☐ Do you have a Quality Assurance Program?
- ☐ Are you enrolled in a Patient Safety Organization?

YES NO PHARMACY OPERATIONS

- ☐ Are staff members trained on CMS 10147 Adherence if a "569 error" occurs?
- ☐ Do you have Policies and Procedures (P&P) to meet Pharmacy Medicare Part D credentialing requirements?
- ☐ ☐ Are you keeping annual records of all trainings (HIPAA & FWA with 10 years of retention)?
- ☐ ☐ Do you review your EQuiPP scores monthly?
- ☐ Do you have a Medication Adherence Program?

Do you have P&P's for:

- ☐ Usual and Customary
- ☐ Patient Counseling Practices
- ☐ Mis-fill Procedures
- ☐ Medication Recall Procedures
- ☐ Medication Expiration Procedures
- ☐ Generic/Brand Price Disclosures
- ☐ Demographics and Allergy Capture
- ☐ Partial Refills
- ☐ Return to Stock

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Maryland Pharmacists Association, 9115 Guilford Road, Suite 200, Columbia, MD 21046, call 443.583.8000, or email aliyah.horton@mdpha.com.

Special thanks to Graphtech, Advertising Sales and Design

President's Pad

Dear Fellow MPhA Members,

Hello Everyone! I hope you had a wonderful summer! It is truly an honor and pleasure to serve the members of the Maryland Pharmacists Association as President. I look forward to this coming year.

I extend great appreciation to the new chair of the Past President's Council Dixie Leikach for her many years of service and leadership to MPhA. I also thank Hoai-An Truong for his leadership this past year and for engaging with me to ensure a smooth transition.

We had a very active year culminating in a fantastic 134th Annual Convention, where pharmacists from around the state convened to learn, network and celebrate the notable accomplishments of our colleagues and friends. I hope you enjoyed yourself at both the CE sessions and social events and enjoy looking at the recap in this issue.

As many of you know I place a high priority on mentoring pharmacy residents and students to assist them in discovering the niche of pharmacy that inspires them, and developing their leadership skills. As Pharmacists, we are natural leaders and key contributors to excellence in patient care. By making connections with our fellow colleagues and becoming actively involved in our profession through MPhA and the MPhA Foundation, we can ensure that Maryland pharmacy remains strong, connected and passionate about the work we do to serve the residents of Maryland, no matter the practice setting.

This year, we will have many exciting opportunities to get involved and engage in pharmacy and our greater community. I encourage you to take time to connect with a committee or a cause, lend your voice, and encourage your colleagues to join MPhA. The more diverse but united voices we have, the better MPhA will be able to serve you, meet your needs and represent the profession on issues that impact our daily ability to practice. Having worked in hospital, chain, managed care and independent pharmacy, I understand the unique challenges and opportunities we face. Our collective voice can serve to expand the role we play in patient care. I believe that we are at a crucial tipping point for pharmacy, on the brink of achieving Provider status which will allow us to provide comprehensive pharmacy services to an even greater number of patients within our state. We have made significant strides in our legislative efforts. By joining together to present one face for Pharmacy in Maryland we have the power to continue to grow our profession in exciting new directions. At the same time our active voice must also work to protect our ability to provide patient care in a way the puts the patient first. MPhA is here to provide the professional development, advocacy tools and resources to make this happen.

Get active, lend your voice, your expertise and experience. We will all benefit.

I look forward to working with many of you as we reconvene in the Fall.

Again, congratulations to all our award winners and others who received recognition the Annual Convention. May they all inspire us!

Sincerely,

Kristen M. Fink

Kristen Fink
President

Editorial

IMPORTANT

UPDATED Information Regarding Maryland Prescription Drug Monitoring Program

New law requires providers to REGISTER with and USE PDMP

The **Maryland Prescription Drug Monitoring Program (PDMP)** was created to support providers and their patients in the safe and effective use of prescription drugs. The PDMP is part of Maryland's response to the ***epidemic of opioid addiction and overdose deaths.***

MARYLAND PDMP FACTS

- Authorized by law in 2011
- Maryland Department of Health and Mental Hygiene (DHMH) program
- Contains data on Rx controlled dangerous substances (CDS) dispensed to patients in Maryland
- Providers get free, online access through **Chesapeake Regional Information System for our Patients (CRISP)**

WHAT IS CRISP?

- State-designated health information exchange (HIE) serving Maryland and the District of Columbia.
- Electronic system connecting all 46 acute care hospitals in Maryland
- Web-based portal gives providers secure access to patient PDMP, hospital and other clinical data

CRISP

LEGAL CHANGES AFFECTING PROVIDERS

On April 26, 2016, Governor Hogan signed into law HB 437 which includes the following legal changes:

1. **Mandatory PDMP Registration for CDS Prescribers & Pharmacists**

   Pharmacists: Licensed pharmacists in Maryland must be registered with the PDMP by **July 1, 2017.**

   Prescribers: Beginning October 1, 2016, practitioners authorized to prescribe CDS in Maryland must be registered with the PDMP prior to obtaining a new or renewal state CDS Registration (issued by the Division of Drug Control) OR by July 1, 2017, whichever occurs sooner. This applies to physicians, physician assistants, nurse practitioners, nurse midwives, dentists, podiatrists and veterinarians. This mandate does not apply to nurses.

   REGISTER NOW with the PDMP through CRISP at https://crisphealth.org/. Click on PDMP 'Register' button on the left-hand side of the screen. For registration help, call 1-877-952-7477.

2. **Mandatory PDMP Use by CDS Prescribers & Pharmacists**

   Beginning **July 1, 2018**:

   - **Pharmacists must** query and review patient PDMP data prior to dispensing **ANY** CDS drug if they have a reasonable belief that a patient is seeking the drug for any purpose other than the treatment of an existing medical condition.
   - **Prescribers must**, with some exceptions, query and review their patient's PDMP data prior to initially prescribing an opioid or benzodiazepine **AND** at least every 90 days thereafter as long as the course of treatment continues to include prescribing an opioid or benzodiazepine. Prescribers must also document PDMP data query and review in the patient's medical record.

   Information regarding Mandatory Use is available on the DHMH PDMP website. DHMH will provide additional information and reminders closer to, but before the implementation date.

3. **CDS Prescribers & Pharmacists May Delegate PDMP Data Access**

   Prescribers and pharmacists may delegate healthcare staff to obtain CRISP user accounts and query PDMP data on their behalf. Delegates may include both licensed practitioners without prescriptive authority and non-licensed clinical staff that are employed by, or under contract with, the same professional practice or facility where the prescriber or pharmacist practices.

TO LEARN MORE

Visit the DHMH PDMP website for updated information, important compliance dates and Frequently Asked Questions: http://bha.dhmh.maryland.gov/PDMP.

For more information about the opioid addiction and overdose epidemic in Maryland and what healthcare providers can do to help, visit http://bha.dhmh.maryland.gov/OVERDOSE_PREVENTION/.

Version 2.0, June 6, 2016

What has MPhA been doing?
Member Mentions highlighted below!

Congratulations to Kristen Fink and Andrew Wherley
Kristen and Andrew welcomed Baby Boy John Andrew Wherley on May 25, 2016.

Maryland Appointees to APhA 2016-2017 House of Delegates

The following MPhA members will serve as the Maryland Delegation in the APhA 2016-2017 House of Delegates: G. Lawrence Hogue; Brian Hose; Anne Lin; Ashley Moody; Matthew G. Shimoda; Hoai-An Truong; and *Alternate:* James Dvorsky

Medical Mission Trip to Haiti

Hoai-An Truong and Frank Nice travelled to Haiti with students from the University of Maryland Eastern Shore on a pharmacy medical mission trip. The mission brought donated pharmacy and healthcare supplies and assisted with patient care.

Source: Hoai-An Truong

PHARMACY SCHOOL HIGHLIGHTS

Governor Larry Hogan Spring Visit to University of Maryland Eastern Shore

President Juliette B. Bell, Dean Rondall E. Allen, faculty and students at the University of Maryland Eastern Shore School of Pharmacy and Health Professions welcomed Governor Larry Hogan and members of the Maryland House and Senate to campus this past Spring. The visit was an opportunity to express appreciation for funding the planned pharmacy and health profession facility for the school.

Elizabeth Seton High School's Pharmacy Technician Training Program Partners with Notre Dame of Maryland University School of Pharmacy

Dr. Paul Vitale, Interim Chair & Associate Professor of Clinical & Administrative Sciences was invited to assist Elizabeth Seton High School in the evaluation of a pharmacy technician curriculum for its new pharmacy technician training program. At his recommendation, Dr. Barbara McHenry, a licensed pharmacist with over 35 years of experience, was hired as the program coordinator. The program is accredited by the Maryland State Board of Pharmacy. Dean Anne Lin attended the White Coat Ceremony of the inaugural group of students and Mr. Daniel Ashby, Senior Director of Pharmacy, Johns Hopkins Hospital was the keynote speaker. Twenty-eight students along with Dr. McHenry visited Notre Dame during the spring semester and utilized the Pharmacist Care Lab facility for a three-hour sterile preparations class. School of Pharmacy faculty along with Dr. McHenry taught sterile technique. The School of Pharmacy and Elizabeth Seton High School will explore further opportunities for collaboration. Elizabeth Seton is the only college preparatory high school in the state of Maryland that is officially accredited by the Maryland State Board of Pharmacy for its Pharmacy Technician Program.

Editorial

Pharmacy and The Law

By: Don. R. McGuire Jr., R.Ph., J.D.

*This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.*

NEW ADVANCES

We are entering another period of change in the pharmacy profession. We experienced such a period during the 1990's when collaborative practice and pharmacist-administered immunizations were new topics of conversation. Now we are seeing an enhancement of pharmacist-provided, patient-centered services. And these changes are dovetailing with the drive for provider status for pharmacists. I remember performing kinetic dosing for aminoglycosides at our hospital in the 1990's. We were very proud of how progressive and advanced we were. Our results were improving our patients' outcomes. It was only later that we discovered that collaborative practice wasn't yet authorized by our state practice act.

At the opposite end of the spectrum from those who blindly race ahead are those who resist such changes. These are pharmacists who are comfortable in their existing practices and are worried about the extra liability when performing new patient care services. These extra liability concerns have been discussed in previous articles. Change and progress are necessary to stay relevant and useful in the modern world. The key to managing change is preparation.

Ohio enacted a law at the end of 2015 that enhanced the ability of pharmacists and physicians to enter into collaborative practice agreements. Among the authorities granted to pharmacists are; ordering blood and urine tests, analyzing those results, modifying drug regimens (including ordering new drugs), and authorizing a refill of critical medications. Oregon has a new law going into effect in 2016 which authorizes pharmacists to prescribe self-administered oral or transdermal birth control. California has also passed a law similar to Oregon's. Typically these statutes authorize pharmacists to expand their practices, but they do not require them to do so. So how do you prepare to expand your (and your patients') horizons?

Examine the new practices open to you in your state. Which of them are you currently competent to perform? Which can you obtain addition training relatively quickly and become competent? Which ones best serve the needs of your patients? Once you know that, you can assess your liability exposure in performing those services. This is done by reviewing your legal duties to your patients. What duties are required for you to provide the service? What possible ways could those duties be breached? What possible injuries could result from that breach? In this way, you can evaluate your exposure for providing any new service.

Once you have decided to move ahead, the next step in preparation is to examine your insurance coverage. You can't just assume that new practices are covered. Individual insurance companies can determine what they do and do not want to cover in a policy, regardless of what constitutes the scope of practice in your state. It is never safe to assume that you have coverage for something without first asking and validating that with your insurance carrier. For example, there are policies available in the marketplace that exclude damages resulting from patient counseling – whether or not the counseling is required by law. While we are talking about optional activities and services here, your insurance policy should certainly cover the activities that you are required to perform. To avoid problems later, it is a good practice to read your insurance policy to make sure that it provides the coverage that you need.

Once you have assessed your possible exposure and verified your insurance coverage, you are ready to begin providing advanced services like those authorized in Oregon, Ohio, California and other states. You are part of the next wave of change in pharmacy practice. The profession of pharmacy has come a long way in a relatively short period of time. In the 1950's, it was unethical to tell a patient the name of their prescribed medication. Now pharmacist are engaging in extensive collaborative practices, providing MTM and immunizations; even prescribing medications whose names they weren't allowed to disclose a few years ago. It is an exciting time to be a pharmacist!

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

Editorial

Congratulations to the 2016 Graduating Classes!

2016 University of Maryland School of Pharmacy Graduates

Solomon Tesfaye Abera
Sinthi Hau Acey
Oluwadamilola Oyinade Ademiluyi
Kenneth Odianosen Agboifo
Jihye Ahn
Rebecca Oluwatosin Akujor
Seid Beshir Ali
Meharie Getachew Aniley
Kevin Joseph Anthony
Tomefa Asempa
Marie Florence Atana Ebode
Lauren Barbour
Amanda Batdorf
Astrid Rocio Bernal
Michael David Boblitz
Samuel Thomas Brackett
Kelcymarie June Bye
Maria T. Cam
Dianna Lea Williams Campbell
Nicole Caprio
Natalia Victor Ceaicovscaia
Wai Lap Chan
Wai-Yee Chan
Chun-Wei Chen
Jonathan David Chen
Tatiana Petrovna Chentsova
Andrea Wing-Yun Cheung
Boradette Evelyn Chhuan
Yiu-Cheung Frederick Chim
Jane Ching
Brittany Carroll Couto
Moses Oluyanju Demehin
Anupama Divakaruni
Laurence Megne Djatche
Jeanne Diem Ngoc Do
Christine Duan
Emily Elizabeth Dunn
Jasmine Monique Ebron
Emmanuel Kelechi Ezedike
Opeoluwa Innocent Fagbemi
Carly Nicole Fisher
Christina Ebune Fomuso
Batsheva Beth Frank
Miguel Julio Franquiz
Joseph Adam Goble
Michael Ross Goldenhorn
Nancy Guan
Lauren Catherine Haggerty
Lucy Jeamin Hahn
Mahya S. Hajghassem
Naim Haque
Adrienne Isabella Herman
Grace K. Herr
Chi-Cheng Michael Ho
Rebecca Rose Hollins
Alexandra E. Holmes
Chih-Wei Hsu
Suzan Hua
Helen Ping Huang
Sara Yun-Sang Huh
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Cover Story

134th Annual Convention

Martha N. Bryan

The Opening Session Speaker at the 134th Annual Convention presented on Keeping Cool, Calm & Collected when the Pressure is On. This article is provided as a follow-up to her presentation and is DEDICATED TO THOSE WHO WANT TO GET MORE "LIFE" OUT OF LIFE!

All of us want to live longer and enjoy life more, but in our search for healthier living we have overlooked the most important element. Each year we spend more and more money on diets and diet pills, exercise programs, wellness books and videos, vacations, and health club memberships; but the key to a healthy, happy life is to "enjoy our work." When we are fully engaged in work we enjoy, we are at our very best, we are happiest, and we are healthiest.

George Bernard Shaw said, "A master in the art of living knows no sharp distinction between their work and their play, their labor and their leisure, their mind and their body, their education and their recreation . . . They simply pursue their vision of excellence through whatever they are doing and leave others to determine whether they are working or playing." John Gardner in his book *Self - Renewal* said, "The last day you will ever work is the day before you fall in love with whatever you are doing for a living."

When a person is making a success of something, it is not work — it is a way of life.

A survey asking people to select the top ten business people America produced in the past 200 years concluded that the average age of death for achievers like Ford, Bell, Sanders, and Penney was 87. These people were all in professions that are considered to be highly stressful, but each found tremendous joy in their work.

People who enjoy their work are those who know what they want and deliberately do the things that will lead to getting them what they want. They put their whole heart and soul into using their unique talents and abilities to make a difference in the world.

Health comes from the direction in which we are moving. We are happiest when we are thinking planning, working, and climbing in pursuit of our own goals. We are at our best emotionally, mentally, and physically when we are on the road to something we want to bring about

Health and happiness comes when we dedicate ourselves to the development of our natural talents and abilities.

And, health comes by doing what we love to do and doing it better and better in service to others.

To make that happen, we need to commit ourselves to a cause that is greater than us. We will need to fill our thoughts with purpose, our future with a plan, our days with work, our leisure with good friends and family, and our mind with good memories. That is to have succeeded!

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Cover Story

2016 Awards and Recognitions

Bowl of Hygeia Award presented to Ellen H. Yankellow, PharmD.

Established in 1958, the Bowl of Hygeia Award recognizes pharmacists who possess outstanding records of civic leadership in their communities and encourages pharmacists to take active roles in their communities. In addition to service through their local, state, and national pharmacy associations, award recipients devote their time, talent, and resources to a wide variety of causes and community service.

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- All awards presented by MPhA President Hoai-An Truong, unless otherwise noted.

MPhA Mentor Award presented to James Bresette, PharmD

Distinguished Young Pharmacist Award, sponsored by Pharmacists Mutual Companies, presented to Ashley E. Moody, PharmD, BCACP, AE-C

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Salematou Traore, PharmD with Aliyah N. Horton, CAE (right)

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Nghia Nguyen, PharmD with Dean Anne Lin (right)"

Cardinal Health Generation Rx Champions Award, sponsored by Cardinal Health Foundation, presented to Tali Johnson, PharmD (right) by insert name

MPhA Seidman Distinguished Achievement Award presented to G. Lawrence Hogue, BS Pharm, PD

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When to Say When:

The Use and Overuse of Oral Proton Pump Inhibitors

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Introduction

Proton pump inhibitors are among the most widely prescribed drugs worldwide, and in the United States.[1] They are the third most widely sold drug class, with annual sales of $13.9 billion.[1] In comparison to other acid-suppressing medications, such as histamine-2 (H2) receptor antagonists, proton pump inhibitors (PPI) are considered to be more potent at effectively inhibiting acid secretion. PPIs work to suppress gastric basal and stimulated acid secretion by irreversibly inhibiting the H+/K+ ATPase pump located on the basolateral side of the parietal cell, resulting in prolonged duration of activity (up to 3 days).[2] Proton pump inhibitors are now FDA approved for healing erosive esophagitis (EE), maintenance of healed EE, risk reduction for development of gastric ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs), short-term treatment and maintenance of duodenal ulcers, pathological hypersecretory diseases such as Zollinger-Ellison (ZE) syndrome, and as a part of a multidrug regimen for *Helicobacter pylori* eradication (Table 1).[3,4]

As a result of being well tolerated and highly effective, PPIs have become one the most prescribed classes of medications in primary and specialty care, and over-the-counter availability has further increased their use.[1] However, overuse of these medications occurs as many patients continue to take a PPI beyond the recommended duration of therapy. Consumers often take an over-the-counter PPI without an initial or follow-up assessment, and continue therapy beyond the recommended course of therapy. With long-term use (4 months to >2 years), there are many different side effects that can occur such as atrophic gastritis, carcinoma, *Clostridium difficile* associated disease (CDAD), fractures, hypomagnesemia, interstitial nephritis and vitamin B12 deficiency.[4] These adverse effects can result in long-term complications requiring hospitalization and/or worsening of other co-existing conditions.

Last, there are various studies showing that no PPI is considerably clinically superior to another; however, there are large price differences among this class of medications. With OTC formulations on the market, now there are much more affordable options available to patients.

Learning Objectives

After reading this article, the learner will be able to:

1. List proton pump inhibitors on the market and differentiate between prescription and nonprescription formulations.
2. List the indications for available proton pump inhibitors and recommended duration of therapy for each indication.
3. Describe and explain adverse effects from long-term use of proton pump inhibitors and the proposed mechanisms of action.
4. Given a patient case, select a proton pump inhibitor and provide three patient counseling points.

Key Words

- Proton pump inhibitor (PPI)
- Acid-suppressing
- Lansoprazole
- Esomeprazole
- Rabeprazole
- Adverse effects
- Omeprazole
- Dexlansoprazole
- Pantoprazole
- GERD

Sidebar Case

Prescribing Considerations

You're working in your pharmacy one day when RJ, a 58 year-old overweight man approaches the pharmacy counter, and tosses down a box of Prilosec OTC. "This is the FIFTH time I've had to buy this stuff for my indigestion. Why isn't it working?" When you question him, he says that most days he experiences a burning sensation behind his breast bone, and occasionally up his neck. At least several times a week he burps and has acid regurgitation. He frowns when he admits, "Sometimes the chest pain is so severe I worry I'm having a heart attack." He states he has taken four, two-week courses of Prilosec OTC in the past four months (with a two-week hiatus in between courses) and it doesn't seem to be helping. He says he feels a little better while he's taking the Prilosec OTC, but the symptoms go back to baseline severity during the two-week hiatus.

What is your assessment of RJ's symptoms as he's described them?

a. Typical symptoms of simple heartburn

b. Sounds like simple heartburn and possibly gastroesophageal reflux disease (GERD)

c. Symptoms seem suggestive of peptic ulcer disease

d. Symptoms are classic dyspepsia only

The burning sensation and movement toward the neck are suggestive of simple heartburn. However, RJ also states he has acid regurgitation several times a week which suggests GERD. Therefore, the correct answer is B.

Do you recommend RJ purchase this box of Prilosec OTC for the fifth time?

a. Yes

b. No, he should switch to lansoprazole 15 mg (Prevacid 24HR)

Adverse Effects

Vitamin B12 Deficiency

Although there is not enough evidence that proves a direct correlation between vitamin B12 deficiency and long-term (>2 years) proton pump inhibitor use, some studies have shown that there may be evidence of an association. Gastric acidity and pepsin enable the release of ingested vitamin B12 from its protein-bound state; subsequently through a series of steps, vitamin B12 is ingested through the terminal ileum via intrinsic factor[5]. Since gastric acidity is involved in the initial cleavage of vitamin B12, there may be a link of long-term proton pump use and B12 deficiency. This, however, may not create an issue in normal, healthy adults that have a large functional reserve of B12 because the usual human diet contains more B12 than required.[5] Patients on long-term proton pump inhibitor therapy can also still produce intrinsic factor which allows for reabsorbing enterohepatically-recycled cyanocobalamin and retaining ability to absorb unbound cobalamin.[5] Problems with B12 deficiency may become an issue for elderly patients who have a higher prevalence of vitamin B12 deficiency, those who are malnourished, and individuals with lower B12 stores.

Clostridium-difficile associated diarrhea

Clostridium difficile is an anaerobic, spore-forming bacterium that is a leading cause of nosocomial infectious diarrhea in adults.[6] Though the exact mechanism is unclear, it is proposed that proton pump inhibitors increase the pH of the stomach, allowing for bacteria overgrowth and increased risk of infection by many different pathogens including *Clostridium difficile*.[6,7] Bacterial overgrowth increases the level of unconjugated bile acids in the stomach which in turn support the conversion of ingested *C. difficile* spores to the more virulent vegetative form.[5] Mild to moderate *C. difficile* symptoms include mild to moderate watery diarrhea without blood, along with abdominal cramping; however more severe cases can include symptoms of fever, malaise, and high-volume diarrhea.[6] As the infection becomes systemic, more serious complications include pseudomembranous colitis and sepsis.[6] The risk for *C. difficile* infection is the greatest for patients who are chronically ill, immunosuppressed, and/or on antibiotic therapy, especially in the inpatient setting.[5] Long-term use of PPI therapy should be evaluated especially in cases of serious or recurrent enteric infections if there is no urgent indication for acid suppression.[5,8] If possible, use the lowest dose and shortest duration of PPI therapy appropriate for the condition being treated.[8]

Carcinoma

Although the risk of developing gastrointestinal cancer from proton pump inhibitors is extremely low especially in patients without *H. pylori* infection, long-term proton pump inhibitor use with *H. pylori* infection is associated with gastric inflammation and development of atrophy.[5] Acid-suppressing drugs such as PPIs alter the gut environment through acid suppression, thereby increasing the pH of the stomach.[7] The more alkaline environment of the stomach allows for bacterial growth which can cause inflammation of the stomach and altered signaling between cells of the stomach.[9] Two cells involved in cell signaling and

c. No, he should switch to omeprazole 20 mg/sodium bicarbonate 1100 mg (Zegerid)

d. No, he should be referred to his primary care practitioner

RJ is a mess! Five courses of Prilosec OTC? Clearly this isn't getting the job done. Actually RJ has several contraindications to self-treatment including the following:

- Frequent heartburn for more than 3 months
- Heartburn while taking recommended dosages of nonprescription PPI therapy
- Severe heartburn and dyspepsia

RJ should be referred to his primary care provider at this time and he should NOT purchase the Prilosec OTC. Therefore, the correct answer is D.

Several weeks later RJ returns to the pharmacy with a prescription for a PPI. He tells you he's had several medical tests and it seems that he has severe reflux disease. The doctor told him he would be taking this prescription PPI for the foreseeable future. RJ asks "My wife checked this out on the computer, and she's worried about the side effects if I keep taking this medicine. Should I be worried?"

Which of the following MAY be adverse effects associated with long-term PPI therapy?

a. Vitamin B12 deficiency

b. Clostridium-difficile associated diarrhea

c. Fractures

d. Hypomagnesemia

e. All of the above are POSSIBLE side effects; encourage RJ to keep all appointments with his primary care provider

As you read in this article, all of the adverse effects shown above have been associated with PPI therapy. This doesn't mean RJ will necessary develop any of these, or other adverse effects associated with long-term PPI therapy. Of course it's advisable that he keep all follow up appointments with his primary care provider. Therefore, the correct answer is E.

production of gastric acid are: enterochromaffin-like cells (ECL cells) and gastrin-producing cells (G cells).[9] Enterochromaffin-like cells are located beneath the epithelium of gastric glands of the gastric mucosa that aid in gastric production via the release of histamine on parietal cells.[9] Gastrin-producing cells, located in the stomach antrum, produce gastrin which serves 2 functions: first, to stimulate ECL cells to produce histamine, and second to directly stimulate parietal cells to produce hydrochloric acid.[9] In the presence of acid-suppressing drugs, G cells continually produce gastrin which acts on ECL cells and can lead to hyperplasia and further to form liner hyperplasia, micro-carcinoids, and carcinoids.[9] Gastrin's action on parietal cells can lead to hypertrophy and hyperplasia.[9]

Fractures

A large nested case-control study conducted by Yang et al. showed the risk of hip fracture was significantly increased among patients on long-term high dose PPIs; the strength of the association increased with increasing duration.[10] Short-term use of PPIs (less than 1 year) regardless of the daily dose is not associated with increased risk of fractures. The theory supporting this association is that an acidic environment in the stomach facilitates the release of ionized calcium from the insoluble calcium salts into soluble calcium salts which then can be absorbed.[11] This proposed theory, however, does not account for ingested soluble calcium; further, PPI therapy may only hinder calcium absorption taken without a meal.[11] The risk for fractures seems greater in patients already presenting with a risk factor such as those who are elderly, on long-term steroid therapy, and those with osteoporosis.[11]

Given the significant morbidity and mortality from hip and other fractures, providers should weigh the risk and benefits of PPI in vulnerable patients.[5] It is recommended to use the lowest effective dose for the shortest duration of time, and to supplement vitamin D and soluble calcium in the form of citrate rather than insoluble calcium carbonate.[3,10]

Hypomagnesemia

Although hypomagnesemia is very rare with PPI use (less than 30 cases since 2006), it is suggested that the possibility of hypomagnesemia is greater with long-term use of PPIs.[5] A few patients with hypomagnesemia received PPIs for only 1–2 years, but most cases were associated with long-term PPI use: 17 of 28 patients (61%) had received PPI therapy for five or more years and eight (29%) for at least 10 years.[5] Normalization of plasma magnesium levels occurred after PPI discontinuation and reoccurred with days after restarting PPI.[12] Although the exact mechanism is unclear and there are many proposed theories, it is thought that PPIs might impair the paracellular transport of magnesium by altering intestinal permeability and tight junction function.[5] Hypomagnesemia may be symptomatic or asymptomatic; severe cases may cause tetany, seizures, and cardiac arrhythmias.[13] Providers should consider obtaining serum magnesium concentrations prior to beginning long-term therapy, especially if taking concomitant digoxin, diuretics, or other drugs known to cause hypomagnesemia; and periodically thereafter.[5,13]

Acute Interstitial Nephritis (AIN)

A nationwide nested case-control study in New Zealand completed by Blank et al showed omeprazole, pantoprazole, and lansoprazole were associated with a significantly increased risk of acute interstitial nephritis resulting in hospitalization compared with past use.[10] Although the risk was low, the risk was substantially higher in older users.[10] The mechanism of AIN is unknown and appears to be an idiopathic hypersensitivity reaction with no relation to dosage, latency, time to recovery, age, or gender.[14] Acute interstitial nephritis (AIN) is characterized by the presence of an inflammatory cell infiltrate in the interstitium of the kidney.[14] Patients with AIN present with nonspecific symptoms of acute renal failure including oliguria, malaise, anorexia, nausea and vomiting.[14] PPI therapy should be discontinued if AIN develops.

Differentiating between PPIs

Proton pump inhibitors on the market are all similar in terms of chemical structure and mechanism of action. The PPIs differ in their pKa, bioavailability, peak plasma levels and excretion which can elicit different characteristics that may align with patient preferences. Lansoprazole/dexlansoprazole and pantoprazole have been shown to be the most bioavailable with the highest plasma levels. Rabeprazole has a slightly faster onset of action due to its pKa whereas pantoprazole is considered the most "gastro-specific" because of its binding to cysteine residues 813 and 822 within the alpha-subunit of the proton pump.[12] However, the clinical relevance of these differences has not been established.[12]

A number of studies have evaluated differences between PPIs and although some show that one PPI may be slightly superior to another PPI, the

Table 1 – Indications and Approved Duration of Therapy for PPIs[3,15]

Proton Pump Inhibitor Indications	Omeprazole	Zegerid	Lansoprazole	Prevpac	Dexlansoprazole	Esomeprazole	Vimovo	Pantoprazole	Rabeprazole
Active Duodenal Ulcer (4-8 weeks)	X	X	X						X
Active Benign Gastric Ulcer (4-8 weeks)	X	X	X			X*			
Erosive esophagitis (4-8 weeks)	X	X	X		X	X		X	X
Symptomatic GERD (4-8 weeks)	X	X	X		X	X		X	X
Heartburn (OTC – 14 days)	X	X	X			X			
H. pylori eradication (10-14 days)**	X		X	X		X			X
Pathological hypersecretory conditions (as long as clinically indicated)	X		X			X		X	X
NSAID associated gastric ulcer prophylaxis (3-6 months)			X			X	X		
Risk reduction of upper GI bleed in critically ill patients (14 days)		X							

*Injection only. For risk reduction of rebleeding in patients postendoscopy for acute bleeding gastric or duodenal ulcers in adults.

**May require additional treatment duration depending on regimen.

Table 2 – Proton Pump Inhibitor Prescribing Information[3,15]

Generic	Brand	Rx/OTC	Generic	Formulations	Dose Range (mg)/once daily	Administration	Combination Product	Monthly Cost
Omeprazole	Prilosec	Rx OTC	Yes	Capsule Packet Suspension Tablet	20-40	Oral	Zegerid	$129.01/ 30 days (Rx)
								$20.14/ 28 days (OTC)
Lansoprazole	Prevacid	Rx OTC	Yes	Capsule Suspension Tablet	15-30	Oral	Prevpac	$176.90/ 30 days (Rx)
								$10.67/ 14 days (OTC)
Dexlansoprazole	Dexilant	Rx	No	Capsule	30-60	Oral		$266.51/ 30 days (Rx)
Esomeprazole	Nexium	Rx OTC	Yes	Capsule Packet IV Solution Tablet	20-40	Oral IV	Vimovo	$255.68/ 30 days (Rx)
								$9.84/ 14 days (OTC)
Pantoprazole	Protonix	Rx	Yes	Packet Tablet IV Solution	40	Oral IV		$368.22/ 90 days (Rx)
Rabeprazole	Aciphex	Rx	Yes	Tablet Capsules	20-60	Oral		$343.43/ 30 days (Rx)

*Prices based off of minimum dose of generic and OTC formulation.

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This program is Knowledge Based — acquiring factual knowledge that is based on evidence as accepted in the literature by the health care professionals.

Directions for taking this issue's quiz:

This issue's quiz on **When to say When: The Use and Overuse of Oral Proton Pump Inhibitors** can be found online at www.PharmCon.com.

(1) Click on "Obtain Your Statement of CE Credits for the first time.

(2) Scroll down to Homestudy/ OnDemand CE Credits and select the Quiz you want to take.

(3) Log in using your username (your email address) and Password MPHA123 (case sensitive). Please change your password after logging in to protect your privacy.

(4) Click the Test link to take the quiz.

Note: If this is not the first time you are signing in, just scroll down to Homestudy/ OnDemand CE Credits and select the quiz you want to take.

CE Questions Answers *from page 23*

1) C; 2) C; 3) D; 4) E; 5) A; 6) A; 7) A; 8) D; 9) C; 10) D

magnitude of the difference is small and of uncertain clinical importance.[12] Any difference in efficacy may not warrant a change in PPI when considering cost-effectiveness. Table 2 compares the PPIs including generic availability, prescription/non-prescription status, frequency of use, and the average monthly cost.[15] As expected, non-prescription or generic equivalents are less expensive than branded products. Nonprescription PPIs may be beneficial for consumers who do not have prescription coverage or occasional heartburn (<2 days/week) and are just as effective as more expensive prescription alternatives.

Conclusion

Given the potential for long-term side effects, it is important for healthcare providers to consider the following regarding PPI therapy:

- Assess whether there is an indication for a PPI
- Periodically assess PPI dosage and frequency
- Assess whether the treated condition is improving
- Consider vitamin supplementation in elderly or at-risk patients
- Reassess whether PPI therapy is still appropriate or should be discontinued.

If there is no longer an indication for PPI use, the PPI should not be discontinued abruptly as rebound acid hypersecretion and reflux can occur. Instead, the PPI dose should be decreased slowly over a period of time. For example, if the current dose is 40 mg of esomeprazole (Nexium) once daily, the dose can be reduced initially to 20 mg once daily for 2-3 weeks. After the patient is stabilized on this dose, the PPI can be switched to an H2 antagonist such as ranitidine 150 mg twice daily. For additional relief of GERD symptoms or gas, over the counter antacids and simethicone may supplement the regimen.

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MPhA News

WELCOME NEW MEMBERS

Laurie Buonaccorsi
Anne Copeland
Sally Doan
Christopher Goldrick
Ahn Hoang
Cheryl Johnson
Michael Jones
Sonia Kim
Crystal King
Emory Lin
Christina Marrongelli
Ashlee Mattingly
Anna Oakes-Riley
Zachary Oleszczuk
Sandeep Saini
Jordan Strieter

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CE Questions

1 Which of the following best describes the mechanism of action of proton pump inhibitors?

A. Float on top of gastric contents, which are less toxic when stomach content is refluxed
B. Blocks the histamine-2 receptors
C. Irreversibly inhibiting the H+/K+ ATPase pump on parietal cell
D. Stimulated sodium bicarbonate secretion from mucosal cells

2 Which of the following is NOT an indication of one of the proton pump inhibitors?

A. Healing erosive esophagitis
B. Risk reduction for NSAID-induced gastric ulcerations
C. Part of a multidrug regimen for *Clostridium difficile* infection
D. Short term treatment of duodenal ulcer

3 If Vitamin B12 deficiency develops subsequent to PPI therapy, when is this most likely to occur?

A. Within the first month of therapy
B. Within the first 3 months of therapy
C. Within the first year of therapy
D. Generally, after at least 2 years of therapy

4 Which of the following increase the risk of PPI-induced *Clostridium difficile* infection?

A. Patients who are chronically ill
B. Immunosuppressed patients
C. Patients who have received antibiotic therapy
D. A and B
E. A, B and C

5 True or False: Although the risk of developing gastrointestinal cancer from PPI therapy is very low, particularly in the absence of *H. pylori* infection, long-term PPI inhibitor use in the presence of *H. pylori* is associated with gastric inflammation and development of atrophy.

A. True
B. False

6 Which of the following variables has been shown to increase the risk of hip fracture with long-term PPI therapy?

A. Longer durations of therapy
B. Patient age
C. Patients receiving a bisphosphonate
D. Patients with low potassium

7 JR is a 72 year old man who has been taking a PPI for 4 years. Which of the following best describes symptoms suggestive of hypomagnesemia?

A. Tetany, seizures, cardiac arrhythmias
B. Muscle weakness, muscle spasms and tachycardia
C. Increased thirst, delirium and nausea
D. Increase thirst, increased hunger and increased urination

8 The development of acute interstitial nephritis (AIN) due to PPI therapy is associated with which of the following variables?

A. PPI dosage
B. Patient age
C. Patient gender
D. None of the above

9 Which of the following is the indication for Prevpac?

A. Active benign gastric ulcer
B. Heartburn
C. *H. pylori* eradication
D. NSAID associated gastric ulcer prophylaxis

10 Which of the following PPIs is available as a parenteral formulation?

A. Esomeprazole
B. Pantoprazole
C. Rabeprazole
D. A and B
E. A, B and C

Answers on page 21

Save the Dates

9/15 — *Board of Trustees Mtg.* **September 15** Sponsorship and presentation by AstraZeneca - *SGLT-2 Inhibition: A Glucuretic Treatment Option for Your Adult Patients with Type 2 Diabetes*

10/27 — *Pharmacists Month Medication Errors CE in cooperation with the U.S. Food and Drug Administration* **October 27**

11/17 — *Board of Trustees Meeting* **November 17**

12/15 — *MPhA Holiday Party* **December 15**

1/19 — *Board of Trustees Meeting* **January 19, 2017**

2/12 — *MPhA 2017 Mid-Year Meeting – DoubleTree Hilton, Columbia, MD* **February 12, 2017**

2/16 — *Maryland Pharmacy Coalition Legislative Day – Annapolis, MD* **February 16, 2017**

All activities held at MPhA Headquarters unless otherwise noted.

Visit www.marylandpharmacist.org to register online or for more information.

The New Normal

DSCSA Compliance Tips: Policy Matters

What is my new normal? The newly enforced Food and Drug Administration's (FDA) Drug Supply Chain and Security Act (DSCSA) requires electronic tracking and tracing of all dispensed prescription drugs and requires a process for product verification in the event of a suspect product and mandatory reporting requirements. These latest regulations bring a new way of life and create a *new normal* when approaching compliance as a part of your day to day business practices. The best way to document standard operating procedures related to DSCSA is to adopt and document policies.

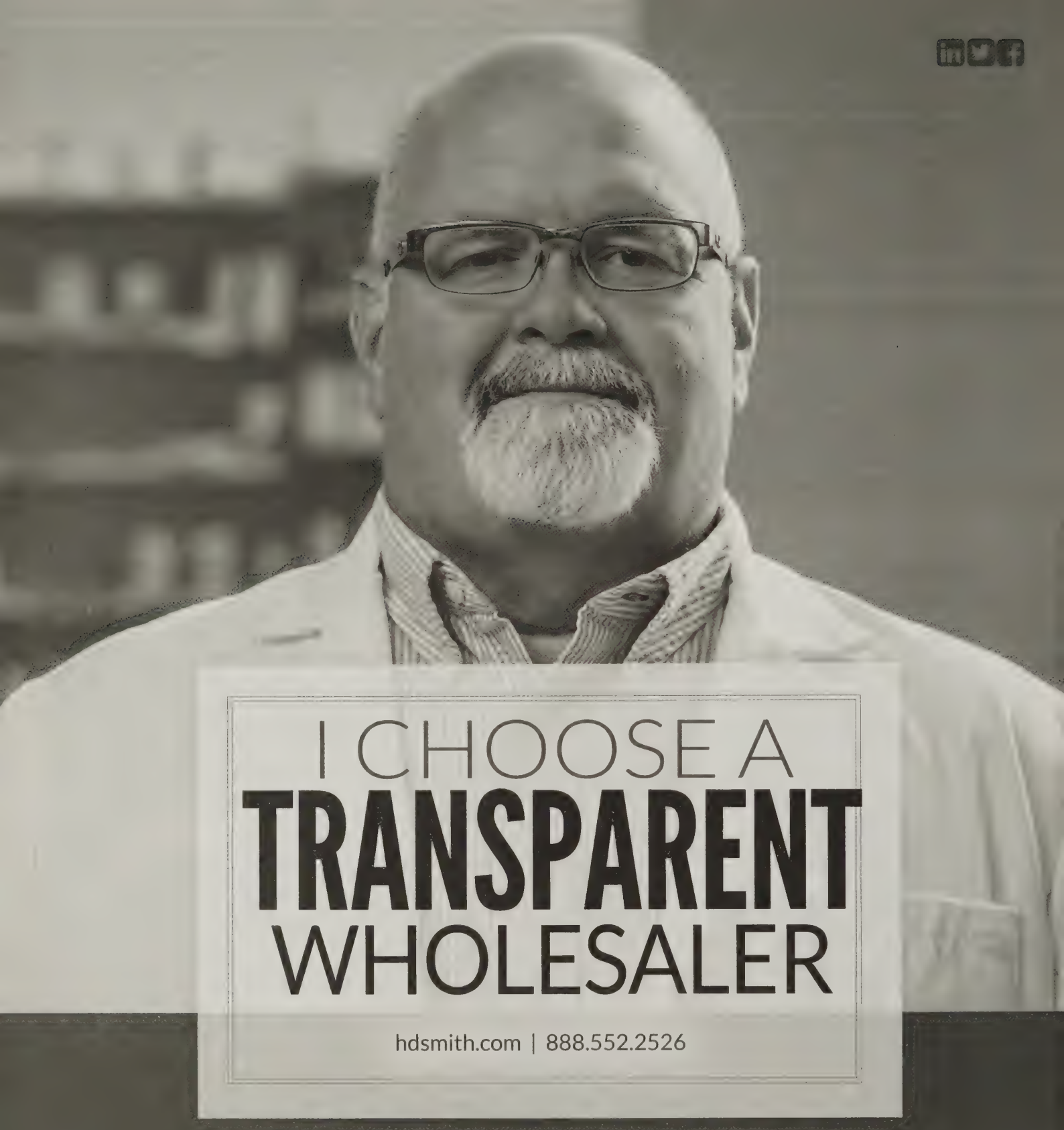
Keeping a policy up to date and easily accessible to staff will bring you real protection and peace of mind!

Developing your Policy and Procedure Manual for DSCSA compliance may seem like a daunting task, especially when considering all of the elements of the new law and what is required of you as a dispenser. A store policy clearly communicates to staff the standard operating procedures for any process, ensuring that all employees handle situations consistently. Adopting a policy is also an important risk management move because, if done properly, it verifies your standard business practices. Even if an employee makes mistakes, evidence of a clear policy and guidelines (which the employee may not have followed) will be helpful to lessen any potential fines or penalties. A clear policy combined with annual staff training is excellent protocol to show compliance with regulatory process requirements.

InfiniTrak, has been following the development of these DSCSA regulations since they began in 2013. When designing a software solution, they looked at the situation from the point of view of the dispenser - and independent pharmacies like yours, and created a tool to meet you needs. For example, InfiniTrak provides its customers with a template for a track and trace policy document to be created to meet each location's requirements.

InfiniTrak is a cost-effective, easy to use software that will save you time and money, increase productivity, ensure full compliance, and provide the peace of mind that comes from knowing that all of your data is at your fingertips, when you need it. Contact us today to learn more about how you can electronically create and transmit FDA and other government reports as required, all in a cloud solution.

Questions regarding your store policy and your compliance plan? Contact info@infinitrak.us.



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Executive Director's Message

What a great 134th Convention!

Members from all over the state gathered in Ocean City, MD to learn, network and celebrate professional and community achievements. This issue is a wonderful visual recap of those balmy days. While we had great fun and learned quite a bit, the House of Delegates also kept us relevant by passing two timely resolutions on medication affordability and the pharmacists role in naloxone.

We have so many pharmacists and student pharmacists who are working hard in their day jobs, while also giving back to the profession via mentoring and volunteering within MPhA and their own communities. It was truly an honor to recognize them during the Excellence in Pharmacy Awards Luncheon. Thank you to all our attendees, presenters, sponsors, contributors and exhibitors for your participation in the 134th Convention.

We are already preparing for the 2017 meetings and looking for your input. Are you doing something new and innovative in your practice setting? We'd love to get you on the program. Please consider responding to our call for abstracts at www.marylandpharmacists.org.

Kudos to our new PharmDs! I have enjoyed getting to know many of the students and attending their celebratory banquets this past Spring. Their education and experiences continue to pave the way for advances in pharmacy practice and our push to achieve provider status. Let us continue to fight for all pharmacists to practice at the top of their training and education!

Since the last publication, we've completed meetings with President of the Senate Mike Miller, members of the General Assembly, as well as with the office of the Insurance Commissioner and Maryland's Attorney General Brian Frosh. We are laying the groundwork for a powerful 2017 legislative session!

Please continue to share your thoughts and ideas with your MPhA leadership and heed our calls to action. Your combined voices provide a chorus that is hard to ignore!

Enjoy the rest of your summer!

Aliyah N. Horton, CAE
Executive Director

Do you know a pharmacy technician ready to take on more responsibility in the pharmacy?

The University of Maryland School of Pharmacy's new, online PharmTechX Program will elevate a technician's abilities and improve the efficiency of your pharmacy.

The PharmTechX Program at the University of Maryland School of Pharmacy offers an online, self-paced, and interactive learning environment designed to help advance a technician's skills and education.

At the end of the program, technicians will be able to:

- Assist with medication management and storage
- Conduct medication profile reviews
- Assist with patients' medication histories
- Complete medication checking
- Monitor for medication errors
- Facilitate improvement of the medication process

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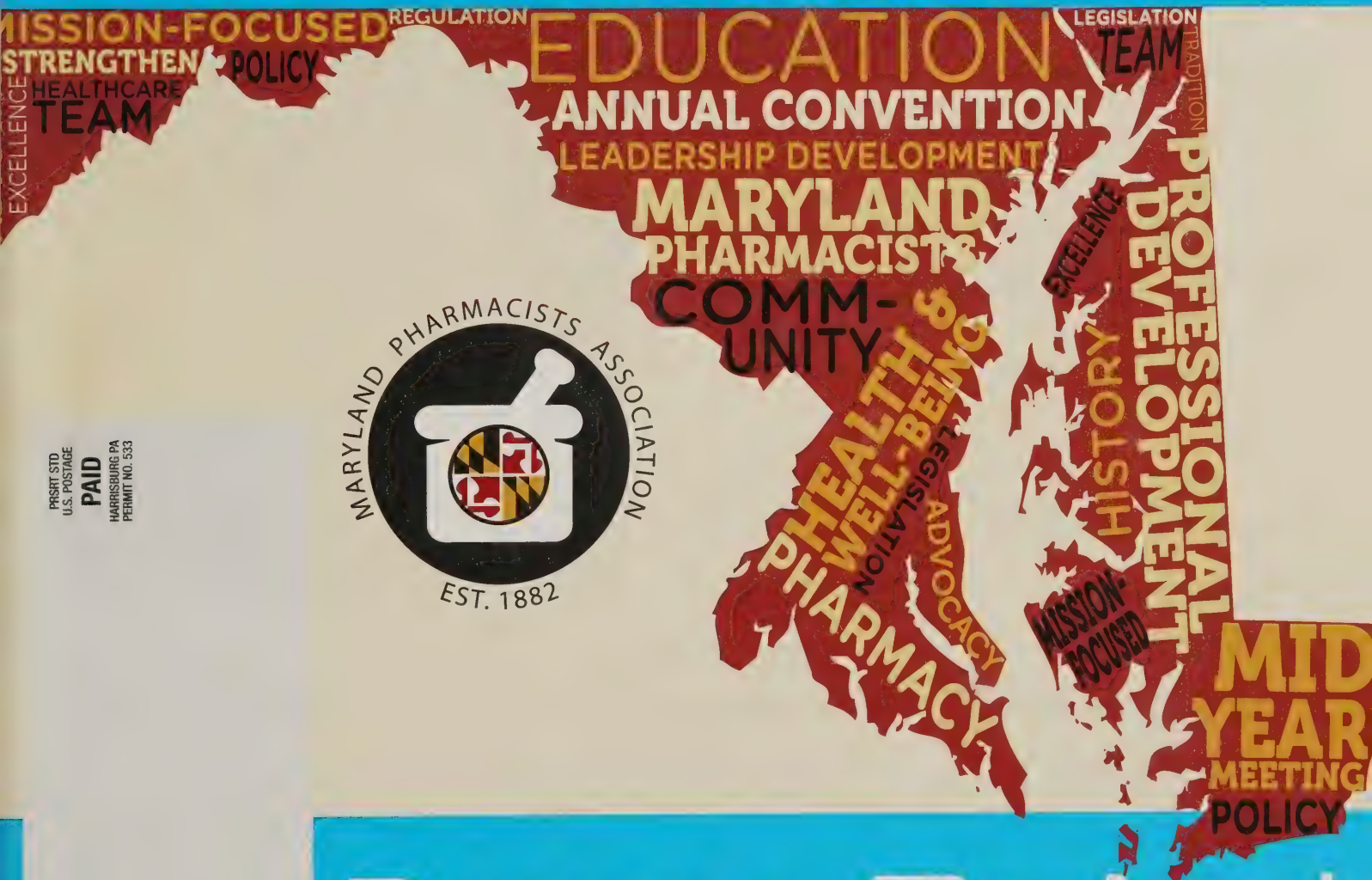
Contact us at *pharmtechrx@rx.umaryland.edu* for more information or visit *www.pharmacy.umaryland.edu/PharmTechX.*

Your Membership Matters - Renew Today!
Now is the time to renew your membership and stay a part of MPhA.

Maryland Pharmacist

FALL 2016

YOUR MEMBERSHIP MATTERS!



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President's Pad

Dear Pharmacy Community,

Hello Everyone! I hope you are having a wonderful Fall and are enjoying the excitement of Pharmacy month! There are many wonderful events taking place to promote pharmacy and our role in quality patient care. There are events focused on professional development to help propel us to the next level of excellence in our careers and events focused solely on celebrating our integral part of the communities we serve. If you have not yet participated in any of these events - please let me encourage you to join us! Too busy this month? It is ok! We have many opportunities each and every month to get involved - as much, or as little, as you would like.

I was recently asked why I am so passionate about the Maryland Pharmacists Association (MPhA). How can I explain what MPhA means to me? For me, the first time I walked into one of the monthly meetings, I felt that I had found a place where I could make a difference and my contributions would be appreciated. The members of this pharmacy family all have a common goal of making our profession the best it can be. Our members are approachable, friendly and upbeat. They can serve as sounding boards, voices of encouragement, voices of experience and sometimes of reason. They want to collaborate and bounce around ideas, and I often find that several of us in a room tend to build upon each other and take an idea to the next level. They inspire me to do more, and I walk away from our meetings energized and excited to be a part of our profession. As an association, we are looking to the future, imagining endless possibilities and doing our best to pave the way to make them a reality. Our mission is to *strengthen the profession of pharmacy, advocate for all Maryland pharmacists, and promote excellence in pharmacy practice.* No one person has to do it all, because as a group, we unite our skills, passions, and interests to form a strong unified voice.

We need you. We need you to join, be active, and participate in the meetings. Volunteer for a committee or event. Share what you are hearing in the community. Share what you would like to see happen or what resources and opportunities you are looking for. Share best practices or challenges. Share your expertise. Share ideas. Share your excitement. Meet others in our profession who want to do the same. By interacting with our colleagues, socially and professionally, we learn from each other and become more interconnected and knowledgeable, allowing us to strengthen our profession and better serve our patients.

Our meetings and convention committee, professional development committee, new practitioner network and technician network are working hard to develop numerous opportunities and events for us to participate in and take advantage of throughout the year. From CE programming to community service opportunities, we are ready to meet your needs. I look forward to hearing from you and seeing you there!

Sincerely,

Kristen M. Fink

Kristen Fink
President

Cover Story

YOUR MEMBERSHIP MATTERS – RENEW TODAY

RENEW YOUR MEMBERSHIP FOR 2017 TODAY!!

- **Advocacy** – MPhA is your voice for legislative and regulatory matters. With your input, MPhA collaborates with elected leaders and other Maryland pharmacy stakeholders to impact pharmacy practice and the public's health. Members engage in the Annual Legislative Day and provide MPhA testimony in Annapolis.
- **Continuing Education and Professional Development** – MPhA offers diverse live CE to ensure you meet your license and certification requirements; and have the tools and resources to support your professional development. Plan to attend the Mid-Year Meeting, Annual Convention and bi-monthly CE events on clinical and policy topics.
- **Communications** – MPhA is your resource for the latest news in the pharmacy industry, around the State, and the Maryland pharmacy community. Through the quarterly journal, *Maryland Pharmacist*, e-newsletter, *Monday Message*, and social media (Twitter, Facebook) MPhA keeps you connected and informed.
- **Professional Recognition** – MPhA serves as portal for nominations to serve on Maryland state pharmacy and healthcare boards, commissions and task forces. In addition, MPhA offers peer recognition via annual professional practice, community service and innovation awards as well as scholarships for students.
- **Networking** – MPhA is excited to have completed a full year in our new home in Columbia, MD. We are more centrally located in the state and offer you a fantastic space to learn, network and advance pharmacy with your colleagues. In addition, our member networks provide opportunities for New Practitioners, Pharmacy Technicians and Federal Pharmacists to engage on issues specific to their needs and careers.

Now is the time to renew your membership. Stay a part of MPhA as the only state-wide professional society representing all practicing pharmacists, pharmacy technicians and student pharmacists. Please renew your membership by logging into your online account at www.marylandpharmacist.org. If you have any questions, please call the office at 443-583-8000. Membership matters!

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Online payment now allows for dues to be paid in a two-part installment plan.

MPHA MEMBER SERVICE PARTNERS

MPhA-specific links and additional information to these partners can be found on the MPhA Resources Page.

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What has MPhA been doing?
Member Mentions highlighted below!

Left to right: Hoai-An Truong, Yen Dang, Magaly Rodriguez de Bittner, and Kyle Melin attended and presented at the International Pharmaceutical Federation (FIP) 76th World Congress of Pharmacy and Pharmaceutical Sciences 2016 in Buenos Aires, Argentina, August 28-September 1 with the theme: "Rising to the Challenge: Reducing the Global Burden of Disease."

Tom Menighan MBA, ScD Named as Vice President to FIP Board

MPhA Member and American Pharmacists Association CEO Tom Menighan has been named as one of the nine vice presidents to the International Pharmaceutical Federation (FIP). Tom most recently served as the 2015-2016 Honorary President of MPhA.

Toyin Tofade, PharmD, MS, BCPS, CPCC is the New Dean of the College of Pharmacy at Howard University

Toyin started her tenure as the new Dean of the College of Pharmacy at Howard University this past August. As Dean, Dr. Tofade will provide direction and leadership, vision and oversight for the College of Pharmacy, reporting to Provost and Chief Academic Officer, Dr. Anthony Wutoh. Dr. Tofade most recently held the position of Assistant Dean and Associate Professor at the University of Maryland School of Pharmacy. She has also served on the faculty of the University of North Carolina at Chapel Hill School of Pharmacy.

Dr. Tofade earned her Bachelor of Pharmacy degree at Obafemi University in Nigeria, and her Master of Science in pharmacy practice and Doctor of Pharmacy, (Pharm D) from the University of North Carolina at Chapel Hill.

Dixie Leikach, RPh, MBA Finalist in Next Generation Pharmacist Awards

Pharmacy Times and Parata systems announced that Dixie Leikach was a finalist in the Civic Leader Category of the Next Generation Pharmacist Awards. Nominations were based on adherence to professional standards, experience as it related to the category and advancement of the profession. Finalists were selected across industry practice settings and were recognized at an awards gala in Boston in August.

Nicole Brandt, PharmD, MBA BCPP, CGP, FASCP has been named the new Executive Director of the Peter Lamy Center on Drug Therapy and Aging at the University of Maryland School of Pharmacy.

Please remember to submit your member mentions to MPhA. Let us all celebrate your personal and professional achievements. Send your updates to admin@mdpha.com.

In Memoriam - Ronald A. Sanford BSP 1944- 2016

Ron Sanford is remembered as a steadfast and active member of the Maryland Pharmacists Association (MPhA). He served as President in 1984 and also as treasurer during his long and active engagement in the organization. His long-time service to MPhA also earned him the Henry Seidman Distinguished Achievement Service Award in 1994. The award recognizes an individual who has made major contributions to MPhA, organized pharmacy and the profession of pharmacy. He was instrumental in changing the name from the Maryland Pharmaceutical Association to its present one.

Ron was a fixture with his son, past President Mark Sanford, at the MPhA Annual Convention, its House of Delegates and Crab Feast held at the Berlin Fire Hall. Many remember him as being the first to begin eating crabs and the last to finish as the volunteer firemen cleaned the entire hall around him.

He also served as President of the University of Maryland School of Pharmacy Alumni Association and later for many years as its treasurer. He loved crunching numbers. Ron received the Honored Alumnus Award from the Alumni Association, is on the Honor Roll of the Life Members of that organization, and was a David Stewart Associate.

Ron was a member of the Wedgewood Club, a group of pharmacy associates and friends, who met every third Thursday of the month for a few drinks, dinner and laughs. Even when Ron was unable to drive, his wife Betty would drive him there and have dinner in another part of the restaurant so that Ron could maintain the friendships that had developed over the years.

Ron was devoted to his chosen profession. But above all, he was devoted to his family. Ron was "a loving husband and father who lived life on his own terms and enjoyed it to the fullest" said Betty. He was proud of Mark's accomplishments following his career in Pharmacy, and of Valerie for her career in Nursing. He loved the ocean where he and Mark had a condo called "Sanford & Son." He loved his family and his cat. His theme song was an old Frank Sinatra tune – "I Did It My Way" – and he did.

Modified from an original statement by friend and colleague George C. Voxakis, PharmD

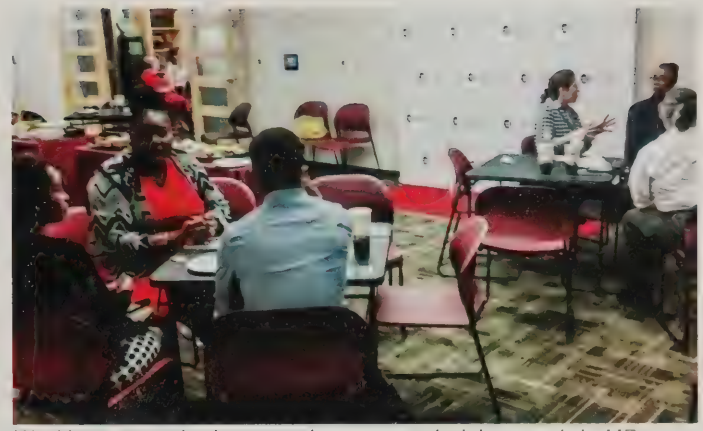
New Practitioner Network and MPhA Foundation FUN-Raiser

The New Practitioner Network (NPN) held a social and fundraising event to support the MPhA Foundation. Partnering with the Baltimore Orioles, NPN participated in the OriolesREACH High-Five Fundraising Program, a unique fundraising effort allowing for $5 of each Orioles ticket sold to be donated to a non-profit organization of their choice. As a way to welcome new practitioners in the area and introduce them to MPhA, NPN hosted a meet-and-greet social at Pratt Street Alehouse before heading over to Camden Yards to see the Baltimore Orioles take on the Washington Nationals in a "Battle of the Beltways." Overall, the fundraiser raised funds for the MPhA Foundation and attendees witnessed an Orioles win (better luck next time Nats!)

Technician Networking Social

The newly formed Pharmacy Technicians Network hosted its inaugural event at MPhA headquarters. The networking social gathered pharmacy technicians from varied practice settings and lengths of practice—attendees included technicians with less than one year of experience to more than 29 years. Chaired by Shelby Holstein and Andrew Wherley, the attendees participated in focus groups and

Co-chairs Shelby Holstein and Andrew Wherley welcome attendees



Working groups brainstorm pharmacy technician needs in MD

fun. The Mid-Year Meeting will feature a Technician Track with content based on feedback from the focus groups. Five CE were given away in a contest from PharmTechX, the Advanced Pharmacy Technician Training Program at University of Maryland, Baltimore and materials were distributed about the Pharmacy Technician Certification Program, sponsored by the Pharmacy Technician Certification Board.

As reminder to Pharmacists and Pharmacy Technicians. The nominations for the 2017 MPhA Pharmacy Technician of the Year Award are open. Nominations may be submitted via the www.marylandpharmacist.org Membership > MPhA Pharmacy Technician Award. The award will be given at the 2017 Mid-Year Meeting on February 12, in Columbia, MD. Deadline December 8, 2016.

Fall Board Meeting

The September board meeting and MPhA kick-off was standing room only! Kristen Fink was formally installed as the 2016-2017 President by Past Chairman Dixie Leikach. Dixie also presented her with the NCPA Pharmacy Leadership Award. The meeting was sponsored by Astra Zeneca and included a presentation by Dr. Daniel Gozzi, Endocrinologist with the Adventist Medical Group. Updates from each Board of Trustees meeting are included in the first *Monday Message* following the meeting

Capitol Hill Health Fair

Rachel Lumish overseeing a bone density test with staff from Rep. John Sarbanes' (D-MD) Office

Monique Spears and Dipen Patel giving Rep. Carter a body composition test

Rep. Carter with Aliyah N. Horton, CAE, MPhA Executive Director

Tolani Adebanjo ensuring documentation is correct for cholesterol and glucose testing

On September 22, American Pharmacists Association (AphA) hosted its 4th Annual Capitol Hill Health Fair. APhA partnered with the office of Rep. Buddy Carter (R-GA), National Association of Chain Drug Stores, National Community Pharmacists Association, the American Society of Health-System Pharmacists and Walgreens to host the event. Student pharmacists from University of Maryland School of Pharmacy, Notre Dame of Maryland University School of Pharmacy and the University of Maryland Eastern Shore School of Pharmacy, as well as schools from Washington DC and Virginia, participated by registering attendees; providing body composition, bone density, blood pressure, cholesterol and glucose screenings; and administering flu shots. MPhA APhA-ASP Student Trustees Rachel Lumish (UMB) and Tolani Adebanjo (UMES) were on site. MPhA's Executive Director had the opportunity to thank Rep. Carter, the only pharmacist in Congress, for his advocacy on behalf of the pharmacy community.

MPhA's Pilot Initiative for "FULL" CRISP Portal Access for Community Pharmacists Set to Launch

Today, through the Chesapeake Regional Information System for Our Patients (CRISP) portal, pharmacists are provided with access to Prescription Drug Monitoring Program (PDMP) data. The role of the community pharmacist has expanded significantly over recent decades; community pharmacists require greater access to clinical information to support care delivery. Access to clinical information beyond PDMP data could, among other things, enable community pharmacists to 1) properly assess controlled substance use 2) enhance medication reconciliation in community pharmacy settings, 3) optimize medication management for chronic conditions, 4) assist patient care coordination and 5) mitigate medication related harm.

The MPhA Pharmacy HIE Access Workgroup, chaired by Jennifer Thomas, was convened to develop recommendations for implementing a limited use case pilot that will inform efforts to expand CRISP services to all community pharmacies. Eight (8) pharmacies have signed on to participate in the pilot initiative: Catonsville Pharmacy, Finksburg Pharmacy, Grubbs Pharmacy, Halethorpe Pharmacy, Independent Drug, Jarrettsville Pharmacy, Sharpsburg Pharmacy and Whitesell Pharmacy. The pilot is scheduled to launch October 2016. Stay tuned for updates on this project and pharmacist access to the "full" CRISP portal.

Improving Transparency and Accuracy in Medicare Part D Spending Act

National Community Pharmacists Association (NCPA) hosted a roundtable discussion and meeting with Rep. John Sarbanes (D-MD) to discuss the needs and concerns of community pharmacy. The group discussed the bill HR 5951/S3308, Improving Transparency and Accuracy in Medicare Part D Spending Act that was set to be introduced. Sponsored by Rep. Griffith Morgan (R-VA) in the House and Senator Shelly Moore Capito (R-WV) in the Senate, the bill amends XVIII of the Social Security Act to prohibit prescription drug plan sponsors and MA-PD organizations under the Medicare program from retroactively reducing payment on clean claims submitted by pharmacies. The bill is intended to improve PBM transparency and ban retroactive DIR fees. MPhA has expressed support for the bill. Rep. Sarbanes has signed on as a cosponsor of the bill. Send a note to thank him.

From L-R: Mark Ey (MPhA Trustee); George Garmer; Mike Wysong; Rep. Sarbanes; Mike Tomberlin of NCPA; and Aliyah Horton.

Tips to Save on Your Student Debt

By: Stephen Dash, CEO, Credible

Many graduates put off refinancing their student loans simply because they don't understand the process, but the average graduate student leaves school with loans totaling over $30,000. MPhA has partnered with Credible to help our members better understand and save on their student debt. The following is a list of common misconceptions debunked.

1. You are stuck with your loans when you graduate
Many graduates refinance their federal and private student loans after graduation because, under certain circumstances, refinancing can result in lower interest rates, lower monthly repayments, and significant savings.

2. Every lender offers similar rates
Depending on the lender, interest rates on student loan refinancing products can range from under 2% to well over 8.0%.

3. Increasing the term of your loan always results in paying more interest
Increasing the term of your loan can still result in less overall

interest if you are able to decrease your rate.

4. Shopping around for the best rate will hurt your credit profile
The credit bureaus treat "rate shopping" as a single credit pull. Inquires made during a focused time period (for example 30 days) have little to no impact on your score.

Overall, there is a great deal of misinformation available about student loans, causing a general lack of understanding. Credible enables MPhA members to compare refinancing offers from multiple lenders side-by-side, and choose the offer that's best for them. To learn more about student loan refinancing, visit Credible on the MPhA Partner Resources Page. ●

© Stephen Dash is CEO of Credible, the leading online marketplace for student loan refinancing.

Have you Checked Out MPhA's Career Center?
MPhA's Career Center is designed to connect talent with opportunity. The career center is the far right button on the MPhA Website. Job seekers can post their resumes and search through job postings as well as set up job alerts, so that available jobs find you! The career center also features a career resources section. The career resources provide everything you need to make your resume stand out, prepare for and ace an interview, advance your career and navigate the job market in the digital age by making sure your social media presence and digital communication styles are working to your advantage.

Once registered in the site, you will have access to the "Ask the Experts" features which gives you the ability to submit a question to a team of trained Coaching Experts. These experts have been working with job seekers including people in career and life transitions for the last twenty years. They are here to answer your questions on refining your resume, preparing for an interview, guiding you through your job research, networking, negotiating or assisting with any other aspect of your job search or career shift.

Employers can customize packages for job notice distributions and for access to resumes posted by job seekers. Visit www.marylandpharmacist.org ●

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Become Engaged

As a member of MPhA, you join a dynamic, interactive group of pharmacists, student pharmacists and pharmacy technicians who are dedicated to improving the health and well-being of Maryland residents. Connect and get involved in a number of committees, from staying on top of important pharmacy legislation on the Advocacy Committee, to reviewing and providing content for the *Maryland Pharmacist*, identifying content and speakers for MPhA's Mid-Year Meeting and Annual Convention, or creating pathways for new opportunities via the Health Information Exchange and Technology Task Force to dozens of other opportunities to volunteer...there is a place for you on an MPhA Committee!

If you are interested in joining one of the Committees or Task Forces or have any questions, please e-mail the Committee Chair. For committee positions appointed by the MPhA President, please contact 2016-2017 President Kristen Fink at finkkristen@gmail.com.

COMMITTEES

Advocacy Committee: serves as an advisory body to Board of Trustees on legislative and regulatory and/other matters that may impact the practice of pharmacy in Maryland. The committee is responsible for reviewing legislative and regulatory proposals; recommending legislative and regulatory priorities to the Board of Trustees; advising on the implementation of any MPhA policies that require legislative action; and representing MPhA on the Maryland Pharmacy Coalition Legislative Committee. The Committee may also work with the Executive Director on specific bills in the Maryland General Assembly.

Chair: Chai Wang, chaifu.wang@gmail.com

Budget and Finance Committee: prepares the proposed annual budget for the Association and presents to the Board of Trustees for approval at least two months prior to the beginning of the fiscal year. The Committee also monitors Association investments to ensure compliance with the Investment Policy Statement.

Chair: Matt Shimoda, drmgshimoda@aol.com

Building Committee: The Treasurer serves as the chair of the building committee which consists of the following persons: Chair of the Board of Trustees, Vice President, Treasurer and two at-large members appointed by the MPhA President. The Committee oversees the financial condition of EFK Properties, LLC and the management of property(ies) owned by EFK Properties, LLC. The Committee reports at least quarterly to the MPhA Board of Trustees

Chair: Matt Shimoda, drmgshimoda@aol.com

Communication Committee: assists staff in telling the MPhA story by promoting and featuring the Association's activities and members. The committee serves in an advisory capacity to identify relevant content for MPhA's digital, social and print media, including our quarterly journal, *Maryland Pharmacist*. The Committee works with staff in identifying subject matter experts; engaging members via social media; and collaborating with other committees to supplement marketing of MPhA meetings and events.

Co-chairs: Deanna Tran and Bonnie Li-MacDonald

E-mail: tran.deanna@gmail.com and bonnie.x.li.macdonald@gmail.com

Constitution and Bylaws Committee: responsible for reviewing the current bylaws and soliciting membership for proposed changes. These recommendations are then submitted to the Board of Trustees for a board opinion and then presented to the House of Delegates for a vote as indicated in the By-Laws.

Chair: Ashley Moody, mccabe.ashley@gmail.com

Meetings Planning Committee: serves as an advisory body to MPhA staff on the theme, program content and schedule for MPhA conferences. The committee works with other MPhA committees to enhance marketing and engagement opportunities for MPhA meetings. The committee also assists staff when needed and acts as a hospitality committee at meeting sites.

Co-chairs: Darci Eubank and Sadhna Katri

E-mail: deuba001@umaryland.edu and anilsadhna@yahoo.com

Membership Committee: comprised of pharmacy professionals, from varied practice areas, who volunteer to personally engage current and potential members of MPhA. The committee serves as a resource and sounding board to MPhA staff on the development of membership recruitment, retention and reclamation strategies and campaigns. The committee works to increase the value proposition of MPhA membership.

Chair: Andrew Haines, andrewhaines2@gmail.com

Nominating Committee: responsible for the presentation of a slate of at least two (2) individuals for each forthcoming available seat on the Board of Trustees and the office of Vice President, and Treasurer (on alternate years) to the House of Delegates at the Mid-Year Meeting. The Nominating Committee shall consider geographic diversity, practice specialty, experience, and the requirements included in the Association's bylaws in making its nominations. The slate of candidates is presented to the House of Delegates at the Mid-Year meeting.

Chair: Cherokee Layson-Wolf, cwolf@rx.umaryland.edu

Preservation Committee: responsible for advising MPhA staff on the upkeep, display, and cataloging of the association's historical pieces. The committee is also responsible for providing content to showcase Maryland pharmacy history via MPhA's quarterly journal and website.

Chair: Doug Campbell, dougstoytrucks@aol.com

Professional Development Committee: responsible for furthering the professional development, including continuing education, of MPhA members and furthering the mission of MPhA in identifying and developing professional projects to expand awareness and educate the public about the value and role of pharmacist services in the healthcare community.

Co-chairs: Amy Nathanson and Virginia Nguyen

E-mail: anathansonrx@gmail.com and vnguyen@umaryland.edu

Resolutions Committee: required to review all submitted resolutions prior to the Annual Meeting and present a report to the Board of Trustees for purposes of determining the Board's position prior to the second House of Delegates meeting for vote. The Committee may also work with members to help formulate resolutions. The resolutions committee is chaired by the Vice Speaker of the MPhA House of Delegates.

Chair: Richard DeBenedetto, radebenedetto@umes.edu

Scholarship Committee: in collaboration with the MPhA Foundation annually reviews applications and awards three scholarships to students attending a school of pharmacy in Maryland.

Chair: Wayne VanWie, wvanwie@comcast.net

NETWORKS

The networks are designed to provide a venue for ongoing collaboration, networking and socializing.

New Practitioner Network (NPN): is a welcoming group for practitioners who have graduated in the past 5 years that eases the transition into Maryland pharmacy practice from student to new practitioner pharmacist. NPN assists young professional members by developing resources, learning and volunteering opportunities relevant to the young pharmacists today, while building a community for the next generation of pharmacists. For more information, visit the **New Practitioner Network** webpage.

Co-chairs: Sam Houmes and Lauren Lakdawala

E-mail: houmes.sam@gmail.com and llakdaw1@jhmi.edu

Past Presidents Network: is comprised of Past Presidents Council (PPC). The group is chaired by the immediate past president of MPhA. As PPC the group administers MPhA's award process and is responsible for the promotion of MPhA

awards and selection of recipients. The group may also recommend nominees for national pharmacy-related awards. The network will provide an opportunity for Past Presidents to engage beyond the awards process.

Chair: Dixie Lekach, finksburgrx@gmail.com

Technician Network: To further develop our technician membership and the purpose and activity will be determined by those who volunteer to be the founding members.

Co-chairs: Shelby Holstein and Andrew Wherley

E-mail: shelby2k3@gmail.com and andrew.wherley@gmail.com

Federal Pharmacists Network: To further develop our Federal pharmacist membership and identify membership services and activities geared toward this cohort.

Co-chairs: Mathilda Fienkeng and Mary Kremzner

Email: mathilda.fienkeng@gmail.com and mary.kremzner@fda.hhs.gov

TASK FORCES

MPhA Task Forces are designed to support a short-term targeted focus on a specific outcome or initiative. It is a great way to work with colleagues and support MPhA with shorter investment of time.

Cruise Task Force: responsible for working with the MPhA staff to investigate and plan of all aspects of any cruises sponsored by MPhA. This includes the choice of travel agents, cruise line and itinerary, continuing education program, and implementation of all activities on site during the cruise. The cruise destination shall be determined based on survey feedback from Membership.

Chair: Arnie Honkofsky and Jim Bresette

E-mail: gbmcarnie1@verizon.net and jlbresette@umes.edu

Health Information Exchange Task Force: Health Information Exchange and Technology responsible for working for community pharmacists access to Maryland's health information exchange, the Chesapeake Regional Information System for our Patients (CRISP). Access to CRISP will provide healthcare information for improved medication management and services and continuity of care.

Chair: Jennifer Thomas, thomasjen@dfmc.org

Maryland's Pharmacists: Improving People's Health

By 2020 there will be an estimated shortage of 20,400 primary care physicians in the U.S. Even if nurse practitioners and physician assistants are fully utilized, patient needs will not fully be met.[1]

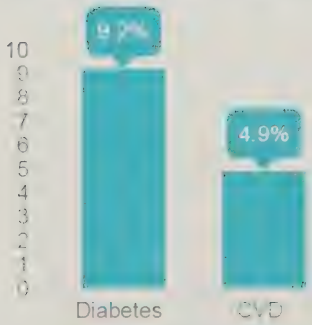
Maryland has a shortage of 160 physicians.[1] The 6,060 highly trained Maryland pharmacists are ready to bridge the gap by providing chronic disease management and wellness and prevention services.[2]

Meeting Patients' Needs in Maryland

5.9 Million people[3]

55% of the physicians needed to deliver care[1]

6,060 Pharmacists ready to help[2]



Prevalence of chronic disease in Maryland [4,5]

Diabetes

Diabetes is a complex condition that is often managed by multiple medications. Pharmacists can optimize care and help patients understand their medications and their condition in order to improve outcomes and avoid complications.[6-9]

Cardiovascular Disease (CVD)

For patients with uncontrolled high blood pressure, waiting even two months to optimize medications increases the risk of complications, including hospitalizations. Pharmacists are highly accessible members of the care team who significantly improve blood pressure control and can provide timely follow-up and monitoring to improve outcomes.[10]

52% of Maryland residents were vaccinated for the flu[11]

Immunization rates across the U.S. have continued to increase since pharmacists began vaccinating.[11]

50% of people with chronic diseases do not take their medicines correctly.[13]

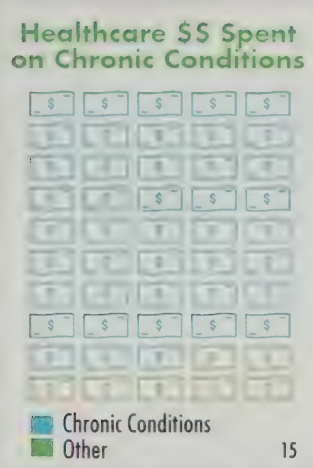
Medications are critical for the treatment of chronic conditions. Pharmacists can help patients use them safely and effectively to avoid medication related problems.[14]

Smoking causes nearly 1 of every 5 deaths in the U.S. each year.[12] Pharmacists are qualified and capable of providing smoking cessation counseling.

15% of people in Maryland smoke cigarettes[12]

Maryland spends $6,321,500,000 annually on prescription medications.[5]

Investing in pharmacists' services optimizes the use of those prescription medications. Decades of research have proven the value of including pharmacists on healthcare teams. Improved health outcomes, lower costs, and increased access to care could be a reality for Maryland residents if pharmacists were fully empowered to serve as patient care providers.



On average **$1,000** per patient per year is saved with pharmacist interventions for patients with chronic conditions.[6-8, 16]

Pharmacists' counseling and adherence programs can save the healthcare system **$164 per patient** in the 6 months following the start of a new prescription medication.[17]

On average, a single hospital readmission in the U.S. costs $11,200 with a 21.2% readmission rate.[5a]

Maryland spends 18.2% of its General Fund Expenditures on Medicaid.[5]

Patients are **3X** more likely to stay out of the hospital when pharmacists provide clinical services after discharge.[18]

Pharmacists in Ohio delivered a 4.4:1 ROI when providing medication therapy management services to Medicaid patients. Maryland pharmacists could do this too![19]

$4.40 saved per $1 spent on pharmacists' services

This information was developed through a collaboration between APhA and NASPA with generous support from the Community Pharmacy Foundation.

References available at www.pharmacistsprovidecare.com

Continuing Ed

Treating opioid-induced constipation:

A community pharmacy perspective

Christine Nkobena, PharmD Candidate 2019

Leah Sera, PharmD, BCPS
Associate Professor, Department of Pharmacy Practice and Science
University of Maryland School of Pharmacy

Learning Objectives

After reading this article, the learner will be able to:

1. Describe the pathophysiology of opioid-induced constipation (OIC).
2. Describe the mechanism of action, adverse effects, and contraindications for drugs and drug classes used to treat opioid induced constipation.
3. Given a patient case, choose an appropriate treatment option for OIC based on patient- and agent-related variables.

Key Words

- Opioid-induced constipation (OIC)
- Stimulant laxatives
- Osmotic laxatives
- Peripherally-acting mu opioid antagonists, PAMORAs
- Pain management
- Palliative care

Introduction

Chronic pain is a significant problem in the United States (US) that affects 100 million people, more than the combined number of patients with diabetes, coronary heart disease, stroke, and cancer.[1,2] Opioids are commonly used to treat chronic cancer-related pain and chronic non-cancer pain (CNCP), with approximately 250 million prescriptions written annually in the US.[3] Constipation is one of the most common side effects of opioid-use, affecting 15-90% of patients with CNCP and up to 90% of patients with cancer pain.[4,5] The discomfort from opioid-induced constipation (OIC) may lead to discontinuation of opioids and consequently to increased pain.[6]

OIC, also called opioid-induced bowel dysfunction, has been defined as "a change, when initiating opioid therapy, from baseline bowel habits, defecation patterns, and what individuals consider normal that is characterized by any of the following: (1) reduced frequency of spontaneous bowel movements; (2) developing or worsening of straining to pass bowel movements; (3) a sense of incomplete rectal evacuation; or (4) harder stool consistency."[7] Opioid receptors are located throughout the central nervous system and periphery, with the enteric nervous system in the gut housing the largest concentration of receptors outside the brain.[8] Opioids bind with mu-receptors in the gastrointestinal (GI) tract and interfere with normal GI function by decreasing peristalsis, inhibiting fluid secretion into the gut, and increasing transit time, which leads to greater absorption of fluid and the development of hard, dry stools.[4,9] The purpose of this article is to review therapeutic options available for the prevention and treatment of OIC.

First Line Treatments

Patients starting on opioid therapy should simultaneously begin laxative therapy to prevent, if possible, the development of OIC. Stimulant laxatives, osmotic laxatives, and stool softeners have traditionally been first line treatments for OIC. Common stimulant laxatives used in the United States include senna, an anthraquinone

glycoside, and bisacodyl, a diphenylmethane.[10,11] These medications directly stimulate the intestinal mucosa to increase peristalsis, and soften stool by altering fluid and electrolyte secretion.[12] Osmotic laxatives commonly used in the treatment of OIC include polyethylene glycol, lactulose, and magnesium salts (e.g., magnesium hydroxide), and act by increasing fecal water content and stimulating peristalsis via distention of the bowel.[13] Refer to Table 1 for prescribing information for first line treatment.

Docusate, which softens stool by facilitating the incorporation of water and fat, has historically been added to bowel regimens in the treatment of constipation. It is unlikely to be useful in the treatment of OIC as monotherapy, as it does not directly address the pathophysiology of this condition.[12] Additionally, a recent clinical trial has called into question the addition of docusate to stimulant laxatives in the treatment of OIC. In this trial, hospice patients were randomized to receive senna twice daily plus either docusate or placebo twice daily. No significant between-group difference was found in stool frequency, volume, consistency, or in completeness or difficulty of evacuation.

Common non-pharmacological interventions for the treatment of constipation include increasing fluid and fiber intake, and increasing mobility.[15] Evidence for the use of non-pharmacologic treatments in functional constipation is conflicting, and there is minimal data regarding the use of these interventions specifically in OIC.[15] Like stool softeners, these interventions do not address the underlying causes of OIC. Some interventions, such as bulk forming agents (e.g., psyllium) may actually be harmful in patients with OIC, since reduced motility prevents movement of bulked up stool and can lead to bowel obstruction.[16]

Newer Agents

Patients who fail to respond to a regimen of first line agents may require targeted therapy. There has been a great deal of interest over the past several years in developing agents which specifically address the actions of opioids in the gut that are responsible for the development of OIC. Methylnaltrexone bromide, a peripheral mu opioid antagonist (PAMORA), was approved in 2008 for the management of OIC in patients with advanced illness and later approved for subcutaneous use in patients taking opioids for CNCP. A double-blind study of patients with advanced illness (e.g., cancer, cardiovascular disease, pulmonary disease) found that more patients had a bowel movement within 4 hours of administration when treated with subcutaneous methylnaltrexone 0.15 mg/kg or 0.3 mg/kg than those treated with placebo (62% and 58%, respectively, vs 14%, $P<0.001$).[17] Similarly, more patients with CNCP had a bowel movement within 4 hours when treated with methylnaltrexone 12 mg daily or every other day than those treated with placebo (34.2% in both groups vs. 9.9%, $P<0.001$). In July 2016, the FDA approved an oral formulation of methylnaltrexone. Methylnaltrexone, which contains a quaternary amine and is therefore unable to cross the blood-brain barrier, is active only in the periphery and therefore does not reverse centrally mediated analgesia.[19] See Table 2 for dosing, precautions, and side effects of methylnaltrexone and newer agents.

Naloxegol was approved in 2014 for the treatment of OIC in patients with CNCP. This drug is a pegylated

Sidebar Case

Prescribing Considerations

Mrs. Smith is a 54-year old woman with low back pain resulting from a motor vehicle collision two years ago. She is well known to your practice. Her primary care physician had been managing her pain with a combination of NSAIDs and acetaminophen. She tried spinal manipulation and physical therapy, however her pain persisted and she underwent spinal surgery four months ago. Initially she experienced some symptom relief, but when the pain worsened she began seeing a pain specialist who prescribed controlled-release oxycodone about a month ago. She returns to the pharmacy today and asks, "What do you recommend for constipation?" Her past medical history includes hypertension, type 2 diabetes, chronic low back pain, and insomnia. Her current medications are as follows: lisinopril 20 mg po daily, verapamil 180 mg po daily, metformin 500 mg po bid, oxycodone controlled-release 10 mg po bid, oxycodone 5 mg q4h prn pain (using 2-3 doses per week), zolpidem 5 mg po qhs.

Which of Mrs. Smith's current medications (other than oxycodone) is most likely contributing to constipation?

a. Lisinopril

b. Verapamil

c. Metformin

d. Zolpidem

The answer is B. Of the antihypertensives, calcium channel blockers are most likely to cause constipation. Metformin is more likely to cause diarrhea.

What first line treatment would you recommend at this time for Mrs. Smith?

a. Senna

b. Senna plus docusate

Table 1. Prescribing Information for First Line Treatments[28]

Drug Name/ Usual Dosing	Mechanism of Action	Warnings/ Precautions	Adverse Effects
Senna 17.2 mg po daily to 34.4 mg po bid	Direct stimulation of peristalsis	Do not use if suspected GI obstruction; undiagnosed nausea or vomiting	Intestinal colic, diarrhea Rectal irritation with suppository
Bisacodyl 10-20 mg po daily Rectal suppository: 10 mg daily			
Lactulose 10-20 grams (15-30 mL) po daily	Osmotic; promote secretion of fluid into the bowel	Magnesium salts are contraindicated in patients with renal impairment	GI upset (bloating and gas especially); electrolyte imbalance
Polyethylene Glycol 17 grams (mix powder with 8oz fluid) po daily			
Magnesium salts Magnesium hydroxide: 400 to 800 mg po daily Magnesium citrate: 195 to 300 mL po daily			

derivative of the mu-opioid receptor naloxone which has limited ability to penetrate the blood brain barrier.[20] Naloxegol was evaluated in two double-blind trials and a total of 1,352 patients with CNCP.[21] Subjects treated with naloxegol 12.5 mg or 25 mg daily had higher response rates after 12 weeks of treatment than those administered placebo (44.4% vs 29.4%, P=0.001). In this study, GI adverse effects were most common and seen more frequently with the 25 mg dose of naloxegol. Pain scores and opioid doses were similar between experimental and control groups. Alvimopan, another PAMORA, is only approved for the prevention of post-operative ileus for patients in the hospital. It is not approved for outpatient use due to the potential for cardiac toxicity with long-term use, and is therefore not covered in depth in this article.[22]

c. Polyethylene glycol

d. Lactulose

A and C are both correct answers. Although there is little evidence to point the way, the best options in this list in terms of efficacy are senna, polyethylene glycol, and lactulose. Adding docusate does not improve outcomes. In regard to tolerability, senna or polyethylene glycol may be better options; patients tend to complain of bloating, flatulence, as well as the taste of lactulose.

Over the course of three months, Mrs. Smith's bowel regimen escalates to senna three tablets bid, polyethylene glycol po daily, magnesium citrate 30 mL po qhs, and mineral oil enema as needed. She comes in to your pharmacy and complains that despite this increasingly burdensome regimen, she still has infrequent bowel movements which require straining to pass. She asks if there are any other OTC products she can try. Upon questioning you find out that her last bowel movement was 5 days ago, which she describes as "a shmear". She complains of fullness, decreased appetite, and nausea and denies vomiting. Additionally, she has tried to skip doses of her long-acting oxycodone to relieve the constipation resulting in less control of her chronic pain.

What course of action do you recommend for Mrs. Smith at this time?

a. Recommend methylcellulose

b. Recommend lactulose

c. Refer to primary care physician

d. Refer to emergency department

The answer is C. Mrs. Smith should be referred to her primary care physician at this time. She has not had a bowel movement in almost a week and is experiencing nausea. She should be evaluated to ensure there is no bowel obstruction or fecal impaction. She may need an enema, manual disimpaction, or treatment with a drug like methylnaltrexone. Methylcellulose, a bulk forming laxative, could increase the risk for obstruction. She is already taking two osmotic laxatives; lactulose would not likely add benefit to this regimen.

Lubiprostone was approved in 2013 for OIC resulting from chronic opioid use for CNCP, and had previously been approved for the treatment of chronic idiopathic constipation and constipation associated with irritable bowel syndrome (IBS).[23] Lubiprostone activates chloride channels in the intestine that increases fluid secretion and motility.[24] In a randomized, double-blind, placebo-controlled study, subjects treated with 24 mcg twice daily had higher response rates after 12 weeks than those treated twice daily with placebo (27.1% vs 18.9%, P=0.030).[25] Because methadone inhibits activations of the chloride channel, patients taking methadone were not included in lubiprostone studies.[25] The efficacy of lubiprostone was compared to senna for the treatment of OIC in post-surgical patients. Both treatments improved constipation symptoms and quality of life with no significant between-group differences. [26]

In the Pipeline

Several classes of drugs are currently being evaluated in clinical trials to broaden the range of treatments available for patients with opioid-induced constipation.[27] PAMORAs currently under investigation include axelopran and naldemedine. Also under investigation is prucalopride, a serotonin (5-HT_4) receptor agonist. Linaclotide is a guanylate cyclase-C agonist which increases intestinal secretions. It is currently approved for idiopathic constipation and IBS and is being studied for use in OIC.

Role of the Community Pharmacist

Aside from educating patients about the benefits and risks of traditional and newer treatments for OIC, community pharmacists can be invaluable in preventing and detecting the condition. Any patient

Table 2. Prescribing Information for Targeted Therapies[28]

Drug Name/ Usual Dosing	Mechanism of Action	Warnings/ Precautions	Adverse Effects
Methylnaltrexone Advanced illness: 8-12 mg subQ every other day CNCP: 12 mg subQ daily or 450 mg po daily	Peripherally-acting mu opioid antagonist	Contraindicated in known/ suspected GI obstruction Dose adjust in renal dysfunction	Abdominal pain, nausea, gas, diarrhea, headache
Naloxegol 25 mg po daily		Contraindicated in known/ suspected GI obstruction Dose adjust in renal dysfunction Avoid use with moderate CYP 3A4 inhibitors; contraindicated with strong CYP3A4 inhibitors	Abdominal pain, nausea, gas, diarrhea, headache
Lubiprostone 24 mcg twice daily	Chloride channel antagonist	Contraindicated in known/ suspected GI obstruction Reduce dose in moderate to severe hepatic dysfunction May cause dyspnea within 30-60 min of dose; resolves within hours	Abdominal pain, nausea, gas, diarrhea, headache

CE Questions

1 Which of the following best describes the primary mechanism of action of bisacodyl?
   a. Increased fecal mass resulting in peristalsis
   b. Antagonism of mu opioid receptors in the GI tract
   c. Direct stimulation of the large intestine resulting in peristalsis
   d. Increased retention of fluid in the bowel resulting in softer stool

2 Which of the following is a red flag symptom indicating a need for triage in a patient experiencing OIC?
   a. Bloating
   b. Hard stools
   c. Decreased appetite
   d. Unexplained abdominal pain

3 Which of the following medications is most likely to increase the risk of developing constipation in a person also taking opioids for pain?
   a. Sitagliptin
   b. Amoxicillin
   c. Amitriptyline
   d. Metoclopramide

4 True or false: Docusate improves stool frequency, consistency, and volume when added to senna.

5 True or false: Bulk forming laxatives may worsen OIC and should not be used by patients taking opioids.

6 Which of the following OTC medications is available as a rectal suppository?
   a. Senna
   b. Bisacodyl
   c. Docusate
   d. Lactulose

7 Which of the following medications must be avoided in patients taking moderate or strong CYP3A4 inhibitors?
   a. Methylnaltrexone
   b. Lubiprostone
   c. Naloxegol
   d. Bisacodyl

8 Which of the following medications must be dose adjusted in moderate to severe hepatic dysfunction?
   a. Bisacodyl
   b. Lubiprostone
   c. Methylnaltrexone
   d. Naloxegol

9 Which of the following medications should NOT be used when treating OIC in patients taking methadone?
   a. Methylnaltrexone
   b. Lubiprostone
   c. Naloxegol
   d. Bisacodyl

10 Which of the following oral PAMORAs was recently approved for the treatment of OIC?
   a. Axelopran
   b. Alvimopan
   c. Naldemidine
   d. Methylnaltrexone

Answers on page 24

Save the Dates

- **10/27** — *Pharmacists Month Medication Errors CE in cooperation with the U.S. Food and Drug Administration* **October 27**
- **11/17** — *Board of Trustees Meeting* **November 17**
- **12/15** — *MPhA Holiday Party* **December 15**
- **1/19** — *Board of Trustees Meeting* **January 19, 2017**
- **2/12** — *MPhA 2017 Mid-Year Meeting – DoubleTree Hilton, Columbia, MD* **February 12, 2017**
- **2/16** — *Maryland Pharmacy Coalition Legislative Day – Annapolis, MD* **February 16, 2017**

All activities held at MPhA Headquarters unless otherwise noted.

Visit www.marylandpharmacist.org to register online or for more information.

Table 3. Contributing factors to constipation[29]

Medications	Functional Factors
• Calcium channel blockers • Anticholinergics (including antihistamines and some antidepressants) • Antipsychotics • $5HT_3$ antagonists • Oral iron	• Poor food/fluid intake • Decreased mobility • Depression • Sedation • Lack of privacy for toileting • Need for assistance with toileting

who receives a new prescription for opioids should be counseled on the potential for OIC. Patients who are taking long-acting opioids, including transdermal patches such as fentanyl or buprenorphine, should also be taking a first line medication (e.g., stimulant or osmotic laxative) to prevent the development of OIC. Although lifestyle modifications alone are unlikely to successfully treat or prevent the development of OIC, addressing contributing factors may be helpful. Pharmacists can help identify other constipating medications in the patient's regimen and may be able to identify and address reversible functional factors (Table 3).

Important counseling points include informing patients that they should ideally be having a soft, easy-to-pass bowel movement daily. Patients who go four days or more without a bowel movement should be referred to their primary care provider. Likewise, patients who present with constipation and red-flag signs or symptoms, such as abdominal pain, nausea, or vomiting, should be triaged to their primary care provider or urgent care. OIC is predictable and often preventable, and pharmacists play an important role in the assessment, education, and care of patients who require opioids for pain management. ●

Special thanks for editorial contributions provided by Kathleen Pincus, PharmD, BCPS

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CE Questions Answers *from page 21*

1) c, 2) d, 3) c, 4) False, 5) True, 6) b, 7) c, 8) b, 9) b, 10) d

Editorial

Third Quarter 2016: Pharmacy Time Capsule

By: Dennis B. Worthen, PhD, Cincinnati, OH

1991

Chicago College of Pharmacy–Midwestern University established at Downers Grove, IL

1966

FDA contracted with the National Research Council to undertake the Drug Efficacy Study Implementation (DESI) Program to determine the efficacy of products marketed prior to 1962.

One of the early effects of the DESI study was the development of the Abbreviated New Drug Application (ANDA).

1941

Baxter introduces the Plasma-Vac container, providing the first means of separating plasma from whole blood and storing it for future use.

1916

The *U.S. Pharmacopoeia* drops whiskey and brandy from its list of drugs.

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Executive Director's Message

What's Your Story?

During my time at MPhA, I've had the opportunity to tell the pharmacists' "story" to members of the public, healthcare stakeholders, elected and appointed officials, as well as friends and family. Each time your story is told, there is a new understanding of the education and expertise you have; the role you play in the healthcare system and in your community; and the opportunities for Maryland residents to receive quality information and patient care from you.

I've also heard your MPhA stories. Many of you joined MPhA through the encouragement of a colleague or friend— you tagged along to one of our public board meetings, felt welcomed, and saw that we were living our mission and values to advance and protect the profession. I've also heard about the friendships that have been forged through volunteering and committee activity; connections built by MPhA recognizing your professional achievements and academic scholarship; and families creating generations of Maryland pharmacists, who have served the organization in both volunteer and leadership capacities. You've also shared stories about the Annual Conventions, the museum, expansion of pharmacy and pharmacy technician education, passage of major legislation, our beloved crab feast, and so many other events and milestones along the way that have created our story.

MPhA! What a legacy and what a place to be! We have more memories to make and more work to do. As we embark on 2017, look to MPhA to continue to share your story, but I also encourage you to do the same. We are stronger when we have more voices in the game. Encourage MPhA membership, bring a friend or colleague to the next MPhA meeting or event, take a young pharmacist or pharmacy technician under your wing, or be prepared to call or meet with a Delegate during Legislative Session. Our Networks for New Practitioners, Federal Pharmacists, and Technicians are creating pathways of activity and engagement where we truly bring together the pharmacy community. We need you AND your colleagues.

We have more memories to make and more work to do. As we embark on 2017, look to MPhA to continue to share your story, but I also encourage you to do the same. We are stronger when we have more voices in the game.

Here's a bit of my story. Not long after joining MPhA, I learned that my great-grandfather had been a pharmacist (I only knew that he was a physician). He arrived on Ellis Island from Jamaica in 1916. The manifest listed his occupation as a druggist. He encountered many trials but eventually opened a pharmacy in a community called Sugar Hill in Harlem, NY. Due to his compassion and care, he was credited with helping many families survive the Great Depression. He later went to medical school, at the age of 47, and served at the Sydenham Hospital into the mid-1970s. His pharmacy remained open until his passing.

This story reminded me of not only of the role pharmacists have and continue to play in communities, but also the ability of this type of career to change the trajectory of a family for generations. So during this Pharmacists Month, I salute all of you and my great-grandfather, Josiah "Doc" Bellamy. ●

Best regards,

Executive Director

P.S. Share your Story at www.facebook.com/MarylandPharmacistsAssociation/

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